contravenes the intent of Congress in enacting the APPA.

III. The Department of Justice's Actions in This Matter Have Totally Contravened Congress' Intention in Enacting the APPA

Congress passed the APPA in response to perceived abuses by the Department of Justice in settling antitrust cases. It was observed that the settlement process was cloaked in secrecy and was subject to political abuse, and that the views of interested third parties were seldom considered. *See* H.R. Rep. No. 1463, 93d Cong., 2d Sess. *reprinted in* 1974 U.S. Code Cong. & Ad. News 6535–40; 120 Cong. Rec. 38585 (1974) (remarks of Sen. Tunney); 120 Cong. Rec. 36341–42 (1974) (remarks of Reps. McClory and Seiberling); 119 Cong. Rec. 24598 (1974) (remarks of Sen. Tunney). The House Report on the APPA states that Congress' intent in passing the APPA was to curb the "[v]arious abuses in consent decree procedures by the Antitrust Division and by district courts" by substituting "sunlight" for "twilight". H.R. Rep. No. 1463, 93d Cong., 2d Sess. *reprinted in* 1974 U.S. Code Cong. & Ad. News 6537. Further, Congress clearly intended that a court analyze whether the proposed consent judgment was in the public interest and not just to act as a rubber stamp. *Id.* at 6538.

To achieve those objectives and open up the consent judgment process to public scrutiny, the APPA establishes several steps that the Department of Justice must take prior to entering into a final consent judgment. First, the APPA ensures that the public has fair notice by requiring that the terms of the proposed judgment and the competitive impact statement be published in the **Federal Register** at least sixty days prior to the effective date of the judgment. 15 U.S.C. 16(b). This is to *ensure* that the public is aware of the proposed consent judgment and has the opportunity for meaningful comment. During the sixty day comment period, the Department is required to receive and consider comments relating to the proposed judgment. 15 U.S.C. § 16(d). At the expiration of the sixty days, the Department is required to file with the court and publish in the **Federal Register** its responses to the comments. *Id.* After the sixty day period, the court is required to make a determination whether entry of the proposed judgment is in the public interest. 15 U.S.C. §§ 16(e) and (f).

In this action, however, there can be no question that the Department knowingly disregarded the requirements and the very purpose of the APPA. Just days after publication in the **Federal Register**, the Department allowed Bayuk to sell its Garcia y Vega assets to General Cigar Co.

The Department did not even bother to tell the Court or American Maize that the transaction was going to happen even though the Staff received ten days advance notice. This practice does violence to, and flies in the face of, the clear meaning and intent of the APPA that the public is entitled to comment and that the Court is not merely to serve as a "rubber stamp" for the Department of Justice. The Department of Justice unilaterally decided that it would not even give the Court the opportunity to "rubber stamp" the proposed final judgment.

It is not in the public interest for the Department to be allowed to submit an incorrect Competitive Impact Statement and to ignore Congressional intent with respect to the APPA. For the foregoing reasons the proposed final judgment should not be entered.

Hall, McNicol, Hamilton, Clark & Murray,

Attorneys for American Maize-Products Company.

[FR Doc. 82-16835 Filed 6-21-82; 8:45 am]

BILLING CODE 4410-01-M

Attorney General

Proposed Consent Decree in Action To Enforce the Clean Water Act

In accordance with Departmental Policy, 28 CFR 50.7, 38 FR. 19029, notice is hereby given that on June 1, 1982, a proposed consent decree in *United States* v. *Louisville and Nashville Railroad Company*, No. 82–0558–C–B, was lodged with the United States District Court for the Southern District of Alabama, Southern Division. The proposed decree provides for settlement of a suit under the Clean Water Act concerning the company's twelve facilities in Alabama, Tennessee and Kentucky. The proposed decree requires that company pay a civil penalty for alleged violations of Section 301 and conform to waste water treatment facility completion schedules and effluent standards.

The Department of Justice will receive, for a period of thirty (30) days from the date of this notice, written comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *Louisville and Nashville Railroad Company*, D.J. Ref. No. 90–5–1–1–1554/90–5–1–1–1154.

A proposed consent decree may be examined at the office of the United States Attorney, Southern District of Alabama, 311 Federal Building, Mobile, Alabama 36602; at the Region IV Office of the United States Environmental Protection Agency, Office of Regional Counsel, Second Floor, 345 Courtland Street, N.E., Atlanta, Georgia 30365; and the Environmental Enforcement Section, Land and Natural Resources Division, United States Department of Justice, Room 1515, Ninth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20530. A copy of the proposed consent decree may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting the proposed consent decree please send a check or money order in the amount of $1.10 (10 cents per page reproduction charge) made payable to the Treasurer of the United States.

Carol E. Dinkins,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 82-16834 Filed 6-21-82; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-12,562]

Baros Coat and Suit Corp.; Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on April 6, 1981 in response to a petition received on March 27, 1981 which was filed on behalf of workers at Baros Coat and Suit Corporation, Brooklyn, New York. Workers produced ladies' suits, coats and jackets.

On December 31, 1979 the Department issued a notice of determination which certified workers at Baros Coat and Suit Corporation, Brooklyn, New York, as eligible to apply for adjustment assistance benefits (TA–W–6268). That certification expired on December 31, 1981, two years after the date it was issued.

Baros Coat and Suit Corporation permanently closed in August 1981. All workers were laid off at that time. These workers were covered by an active certification (TA–W–6268). Consequently further investigation in this case would serve no purpose; and the investigation has been terminated.

Signed at Washington, D.C. this 11th day of June 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 82-16747 Filed 6-21-82; 8:45 am]

BILLING CODE 4510-30-M

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period June 7, 1982–June 11, 1982.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-12,453; Sondra Coat Co., Hoboken, NJ
TA-W-12,257; Fleetline Industries, Inc., Garland, NC
TA-W-12,452; Liberty Fashions, Inc., Hoboken, NJ
TA-W-12,509; Gallant International, Inc., New York, NY
TA-W-12,570; Deltrol Controls, Milwaukee, WI

In the following cases the investigation revealed that criterion (3) has not been met. Increased imports did not contribute importantly to workers separations at the firm.

TA-W-12,896; General Motors Corp., Central Office, Detroit, MI
TA-W-12,897; General Motors Corp., Central Office, Warren, MI
TA-W-12,898; General Motors Corp., Central Office, New York, NY
TA-W-12,899; General Motors Corp., Central Office, Dayton, OH
TA-W-12,900; General Motors Corp., GM Proving Ground, Milford, MI
TA-W-12,901; General Motors Corp., Central Office, Flint, MI
TA-W-12,902; General Motors Corp., Central Office, Chicago, IL
TA-W-12,903; General Motors Corp., Central Office, St. Louis, MO
TA-W-12,904; General Motors Corp., Central Office, Los Angles, CA
TA-W-12,905; General Motors Corp., Central Office, San Francisco, CA
TA-W-12,906; General Motors Corp., Central Office, Washington, DC
TA-W-12,907; General Motors Corp., Central Office, Indianapolis, IN
TA-W-12,908; General Motors Corp., Central Office, Boston, MA
TA-W-12,909; General Motors Corp., Central Office, Kansas City, MO
TA-W-12,910; General Motors Corp., Central Office, Cincinnati, OH
TA-W-12,911; General Motors Corp., Central Office, Honolulu, HI
TA-W-13,068; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Des Moines, IA
TA-W-13,069; General Motors Corp., Chevrolet Motor Div., Zone & Regional Offices, Rockville, MD
TA-W-13,070; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Overland Park, KS
TA-W-13,071; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Wormleysburg, PA
TA-W-13,220; General Motors Corp., Chevrolet Motor Div., Central Office, Warren, MI
TA-W-13,221; General Motors Corp., Chevrolet Motor Div., Zone & Regional Office, Atlanta, GA
TA-W-13,222; General Motors Corp., Chevrolet Motor Div., Zone & Regional Office, Tarrytown, NY
TA-W-13,223; General Motors Corp., Chevrolet Motor Div., Zone & Regional Office, Cincinnati, OH
TA-W-13,224; General Motors Corp., Chevrolet Motor Div., Zone Sales & Regional Office, Irving, TX
TA-W-13,225; General Motors Corp., Chevrolet Motor Div., Zone Sales & Regional Office, Fremont, CA
TA-W-13,226; General Motors Corp., Chevrolet Motor Div., Zone Sales & Regional Office, Oakbrook, IL
TA-W-13,227; General Motors Corp., Chevrolet Motor Div., Zone Sales Sales Office, Homewood, AL
TA-W-13,228; General Motors Corp., Chevrolet Motor Div., Zone Sales Sales Office, Tempe, AZ
TA-W-13,229; General Motors Corp., Chevrolet Motor Div., Zone Sales Sales Office, Santa Monica, CA
TA-W-13,230; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, San Diego, CA
TA-W-13,231; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Denver, CO
TA-W-13,232; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Indianapolis, IN
TA-W-13,233; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Overland Park, KS
TA-W-13,234; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Louisville, KY
TA-W-13,235; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Metairie, LA
TA-W-13,236; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Westwood, MA
TA-W-13,237; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Southfield, MI
TA-W-13,238; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Grand Blanc, MI
TA-W-13,239; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Edina, MN
TA-W-13,240; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Maryland Heights, MO
TA-W-13,241; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Omaha, NE
TA-W-13,242; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Parsippany, NJ
TA-W-13,243; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Bethpage, LI, NY
TA-W-13,244; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Syracuse, NY
TA-W-13,245; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Charlotte, NC
TA-W-13,246; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Fargo, ND
TA-W-13,247; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Parma, OH
TA-W-13,248; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Wayne, PA
TA-W-13,249; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Memphis, TN
TA-W-13,250; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Houston, TX
TA-W-13,251; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Salt Lake City, UT
TA-W-13,252; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Charleston, WV
TA-W-13,253; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Brookfield, WI
TA-W-13,254; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Jacksonville, FL
TA-W-13,255; General Motors Corp., Chevrolet Motor Div., Zone Sales Office, Sanston, VA

In the following cases the investigation revealed that criterion (3) has not been met for the reasons specified.

TA-W-12,389; Krown Manufacturing Co., Inc., Charlotte, MI

The investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of travel and camping trailers are negligble.

TA–W–12,280; Tel-Aviv, Inc., Hoboken, NJ

The investigation revealed that criterion (3) has not been met. Imports did not contribute importantly to workers separations at the subject firm.

Affirmative Determinations

TA–W–12,721; F & D Ladies' Coats & Suits, Inc., Brookyn, NY

A certification was issued in response to a petition received on May 27, 1981 covering all workers separated on or after May 20, 1980 and before March 31, 1982.

TA–W–12,640; Imperial Optical Manufacturing Co., Hialeah, FL

A certification was issued in response to a petition received on April 20, 1981 covering all workers separated on or after June 1, 1980.

TA–W–12,336; Apex Handbags, Div. of Olla Industries, Inc., Weehawken, NJ

A certification was issued in response to a petition received on February 24, 1981 covering all workers separated on or after February 5, 1981.

I hereby certify that the aforementioned determinations were issued during the period June 7, 1982—June 11, 1982. Copies of these determinations are available for inspection in Room 10,332, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20213 during normal business hours or will be mailed to persons who write to the above address.

Dated: June 15, 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 82–16750 Filed 6–21–82; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than July 2, 1982.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than July 2, 1982.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street, NW., Washington, D.C. 20213.

Signed at Washington, D.C. this 14th day of June 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Bon-Art Industries, Inc. (workers)	Fair Lawn, NJ	6/2/82	5/26/82	TA-W-13,522	Plaster products.
Cameron Manufacturing Co. (IUE)	Emporium, PA	5/28/82	5/25/82	TA-W-13,523	Pliers, wrenches, ratchet handles, forgings, custom.
Consolidated Coal Co., Pageton Prep. Plant (workers).	Pageton, W. VA	6/2/82	5/26/82	TA-W-13,524	Coal, preparation.
Clark Equipment Co. (workers)	Georgetown KY	5/28/82	5/24/82	TA-W-13,525	Trucks—forklift, electric.
Davis Hamakua Sugar Co. (ILWU)	Pauuilo HI	6/1/82	5/24/82	TA-W-13,526	Sugar, raw.
Del Monte Corp., Molokai (ILWU)	Kualapuu, HI	6/1/82	5/24/82	TA-W-13,527	Pineapple—grow.
Del Monte Corp., Cannery (ILWU)	Honolulu, HI	6/1/82	5/24/82	TA-W-13,528	Pinneapple—canned, juiced.
Dole Company (Can Plant) (ILWU)	Honolulu, HI	6/1/82	5/24/82	TA-W-13,529	Cans—fruit, juice.
Dole Company (Plantation) (ILWU)	Lanai City, HI	6/1/82	5/24/82	TA-W-13,530	Pineapple—grow.
Dole Company (carnnery (ILWU)	Honolulu, HI	6/1/82	5/24/82	TA-W-13,531	Pineapple—can & juice.
Hadron (workers)	Lake Orion, MI	6/2/82	6/1/82	TA-W-13,532	Machines—transferline.
Hanna Novelty Co., Inc. (workers)	Monticello, IN	6/8/82	5/28/82	TA-W-13,533	Racks—spice.
Hawaiian Commercial & Sugar Company (ILWU)	Puunnene, Maui	6/1/82	5/24/82	TA-W-13,534	Sugar—raw.
Hilo Coast Processing Co. (ILWU)	Pepeekeo, HI	6/1/82	5/25/82	TA-W-13,535	Sugar—raw.
Hilo Iron Works, Hilo Div. (ILWU)	Hilo, HI	4/30/82	4/26/82	TA-W-13,536	Equipment—fabrication.
Inductive Components, Inc. (IBEW)	Hauppauge, NY	6/1/82	5/18/82	TA-W-13,537	Components and transformers electrical.
Jones & Laughlin Corp., Pittsburgh Works (USWA)	Pittsburgh, Pa. (2 plants)	5/25/82	5/11/82	TA-W-13,538	Steel—carbon & products.
Ka'u Sugar Co., Inc. (ILWU)	Phahala, HI	6/1/82	5/24/82	TA-W-13,539	Sugar—raw.
Kekaha Sugar Co., Ltd. (ILWU)	Kekaha, HI	6/1/82	5/24/82	TA-W-13,540	Sugar—raw.
(The) Lihue Plantation Co., Ltd (ILWU)	Lihue HI	6/1/82	5/24/82	TA-W-13,541	Sugar—raw.
Mauna Kea Sugar Co., Inc. (ILWU)	Papaikou HI	6/1/82	5/24/82	TA-W-13,542	Sugar—raw.
McBryde Sugar Co., Ltd. (ILWU)	Eleele, HI	6/1/82	5/24/82	TA-W-13,543	Sugar—raw.
National Steel Corp., Weirton Steel Div. (Independent Steel workers Union).	Weirton W. VA	6/1/82	5/24/82	TA-W-13,544	Tin plant, galvanized sheet hot and cold rolled carbon steel sheet and strip.
Oahu Sugar Co., Ltd. (ILWU)	Waipahu, HI	6/1/82	5/24/82	TA-W-13,545	Sugar—raw.
Olokele Sugar Co., Ltd. (ILWU)	Kaumakani, HI	6/1/82	5/24/82	TA-W-13,546	Sugar—raw.
Pioneer Mill Co., Ltd. (ILWU)	Lahaina, HI	6/1/82	5/24/82	TA-W-13,547	Sugar—raw.
Pirelli Cable Corp. (workers)	Allendale, NJ	5/28/82	5/24/82	TA-W-13,548	Wire—cable, hook-up tubing.
United Technologies, Essex Group, Inc. (workers)	Berrien Springs, MI	5/28/82	5/25/82	TA-W-13,549	Circuits—cut wire & cable.
Wailuku Sugar Co. (ILWU)	Wailuku, HI	6/1/82	5/24/82	TA-W-13,550	Sugar—raw.
Waialua Sugar Co., Inc. (ILWU)	Waialua, HI	6/1/82	5/24/82	TA-W-13,551	Sugar—raw.

[FR Doc. 82–16749 Filed 6–21–82; 8:45 am]

BILLING CODE 4510–30–M

[TA-W-12,828]

Microdot Manufacturing, Inc.; Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 13, 1981 in response to a peition received on July 6, 1981 which was filed on behalf of workers at Microdot Manufacturing, Incorporated, Everlock-Tennessee, Portland, Tennessee.

An active certification coverning the petitioning group of workers remains in effect (TA–W–12,697). Consequently further investigation in this case would serve no purpose; and the investigation has been terminated.

Signed at Washington, D.C. this 11th day of June 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 82-16748 Filed 6-21-82: 8:45 am]

BILLING CODE 4510-30-M

Occupational Safety and Health Administration

North Carolina Standards; Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On February 1, 1973, notice was published in the **Federal Register** (38 FR 3041) of the approval of the North Carolina plan and the adoption of Subpart I to Part 1952 containing the decision.

The North Carolina Plan provides for the adoption of Federal standards as State standards by reference. Section 1953.20 of 29 CFR provides that "where an alteration in the Federal program could have an adverse impact on the 'at least as effective as' status of the State program, a program change supplement to a State Plan shall be required." In response to Federal standard changes, the State has submitted by letter, dated February 5, 1982 from J. A. Wyatt, Acting Director, Occupational Safety and Health Division, North Carolina Department of Labor, to William W. Gordon, Regional Administrator, and incorporated as a part of the State plan, State standards comparable to the following Federal standards: 29 CFR 1910.301, 29 CFR 1910.302, 29 CFR 1910.303, 29 CFR 1910.304, 29 CFR 1910.305, 29 CFR 1910.306, 29 CFR 1910.307, 29 CFR 1910.308, 29 CFR 1910.399 and Appendix A, of Subpart S, dated January 16, 1982; Corrections 29 CFR Part 1910, Fire Protection, Means of Egress, Harzardous Materials, dated May 1, 1981; 29 CFR 1910.19 Special Provisions and 29 CFR 1910.1000 Benzene, amended, dated June 19, 1981; 29 CFR 1910.1028 Benzene, deleted, dated June 19, 1981; 29 CFR 1910.1046 Cotton Dust, deleted, dated June 19, 1981; 29 CFR 1928.113 Cotton Dust in Cotton Gins, deleted, dated June 19, 1981; 29 CFR 1910.95 Noise, Amended and Stays, dated August 21, 1981; 29 CFR 1910.95 Noise, Corrections, dated September 11, 1981; 29 CFR 1910.1025 Lead, amended, dated December 11, 1981; 29 CFR 1910.1043 Cotton Dust, Appendix A, amended, dated October 10, 1980.

These standards were promulgated by filing with the North Carolina Attorney General on May 8, 1981; June 26, 1981; July 13, 1981; December 1, 1981; February 1, 1982 respectively, pursuant to the North Carolina Occupational Safety and Health Act of 1973 (Chapter 295, General Statutes).

2. *Decision.* Having reviewed the state submission in comparison with Federal standards, it has been determined that the state standards are identical to the Federal standards and are hereby approved.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Commissioner of Labor, North Carolina Department of Labor, 4 West Edenton, Raleigh, North Carolina 27601; Office of the Regional Administrator, Suite 587, 1375 Peachtree Street, NE., Atlanta, Georgia 30367, and Office of the Director of Federal Compliance and State Programs, Room N3619, 200 Constitution Avenue, NW., Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds good cause exists for not publishing the supplement to the North Carolina State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are identical to the Federal standards and are therefore deemed to be at least as effective.

2. The standards were adopted in accordance with procedural requirements of State law and further participation would be unnecessary.

This decision is effective June 22, 1982.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667))

Signed at Atlanta, Georgia, this 5th day of March 1982.

William W. Gordon,

Regional Administrator.

[FR Doc. 82-16743 Filed 6-21-82: 8:45 am]

BILLING CODE 4510-26-M

South Carolina Standards; Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On December 6, 1972, notice was published in the **Federal Register** (37 FR 25932) of the approval of the South Carolina plan and the adoption of Subpart C to Part 1952 containing the decision.

The South Carolina plan provides for the adoption of Federal standards as State standards after public hearing. Section 1953.20 of 29 CFR provides that "Where any alteration in the Federal program could have an adverse impact on the 'at least as effective as' status of the State program, a program change supplement to the State plan shall be required." By letter dated February 4, 1982 from Edgar L. McGowan, Commissioner, South Carolina Department of Labor, to William W. Gordon, Regional Administrator, and incorporated as a part of the plan, the State submitted the following amended State standards comparable to Federal Standards: Corrections to Subpart S, 29 CFR Part 1910 Electrical, dated August 7, 1981; 29 CFR 1910.1025 Lead, new

paragraph (e)(1), dated December 15, 1981.

These standards were promulgated after public hearings held on February 4, 1982 and filed with the South Carolina Secretary of State February 4, 1982, pursuant to Act 379, South Carolina Acts and Joint Resolutions, 1971 (Sections 40–261 through 40–274 South Carolina Code of Laws, 1962).

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are identical to the Federal standards.

The State standards are hereby approved.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement along with the approved plan may be inspected and copied during normal business hours at the following locations: Office of the Commissioner of Labor, South Carolina Department of Labor, 3600 Forest Drive, Columbia, South Carolina 29211; Office of the Regional Administrator, Suite 587, 1375 Peachtree Street, NE., Atlanta, Georgia 30367; and Director of Federal Compliance and State Programs, Room N3619, 200 Constitution Avenue, NW., Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds good cause exists for not publishing the supplement to the South Carolina State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are essentially identical to the comparable Federal standards and are deemed to be at least as effective.

2. The standards were adopted in accordance with procedural requirements of State law and further participation would be unnecessary.

This decision is effective June 22, 1982.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667))

Signed at Atlanta, Georgia, this 3d day of March, 1982.

William W. Gordon,

Regional Administrator.

[FR Doc. 82–16744 Filed 6–21–82; 8:45 am]

BILLING CODE 4510–26–M

South Carolina Standards; Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667) (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On December 6, 1972, notice was published in the **Federal Register** (37 FR 25932) of the approval of the South Carolina plan and the adoption of Subpart C to Part 1952 containing the decision.

The South Carolina plan provides for the adoption of Federal standards as State standards after public hearing. Section 1953.20 of 29 CFR provides that "Where any alteration in the Federal program could have an adverse impact on the 'at least as effective as' status of the State program, a program change supplement to the State plan shall be required." By letter dated October 5, 1981 from Edgar L. McGowan, Commissioner, South Carolina Department of Labor, to Karen L. Mann, Acting Regional Administrator, and incorporated as a part of the plan, the State submitted the following amended State standards comparable to Federal Standards:

Section 1910.95 Noise, dated August 21, 1981; Revoked § 1910.1046 Exposure to Cotton Dust in Cotton Gins, dated June 19, 1981; Revoked § 1928.113 Exposure to Cotton Dust in Cotton Gins, dated June 19, 1981.

These standards were promulgated after public hearings held on August 25, 1981 and filed with the South Carolina Secretary of State September 17, 1981, pursuant to Act 379, South Carolina Acts and Joint Resolutions, 1971 (Sections 40–261 through 40–274 South Carolina Code of Laws, 1962).

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are identical to the Federal standards.

The State standards are hereby approved.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement along with the approved plan may be inspected and copied during normal business hours at the following locations: Office of the Commissioner of Labor, South Carolina Department of Labor, 3600 Forest Drive, Columbia, South Carolina 29211; Office of the Regional Administrator, Suite 587, 1375 Peachtree Street, NE., Atlanta, Georgia 30367; and Director of Federal Compliance and State Programs, Room N3619, 200 Constitution Avenue, NW., Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds good cause exists for not publishing the supplement to the South Carolina State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are essentially identical to the comparable Federal standards and are deemed to be at least as effective.

2. The standards were adopted in accordance with procedural requirements of State law and further participation would be unnecessary.

This decision is effective June 22, 1982.

(Sec. 18, Pub. L. 91–596 84 Stat. 1608 (29 U.S.C. 667))

Signed at Atlanta, Georgia, this 8th day of January, 1982.

William W. Gordon,

Regional Administrator.

[FR Doc. 82–16745 Filed 6–21–82; 8:45 am]

BILLING CODE 4510–26–M

Washington State Standards; Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On January 26, 1973, notice was published in the **Federal Register** (38 FR 2421) of the approval of the Washington plan and the adoption of Subpart F to Part 1952 containing the decision.

The Washington plan provides, after public hearing, for the adoption of State standards which are at least as effective as Federal standards promulgated under section 6 of the Act. Sections 1952.120–124 of Subpart F set forth the State's

schedule for the adoption of Federal standards. By letters dated July 12, 1978 and August 12, 1980 from James P. Sullivan, Assistant Director, to James W. Lake, Regional Administrator, and incorporated as part of the plan, the State submitted a State standard and an amendment to 29 CFR 1910.1044—2,3-Dibromo-3-Chloropropane (DBCP). The permanent Federal standard was published in the **Federal Register** (43 FR 11514) on April 4, 1978. The Washington DBCP standard, which is contained in Chapter 296–62–07345 WAC, was promulgated pursuant to 34.04 RCW and of the Open Public Meetings Act of 1979, Chapter 42.30, adopted on June 28, 1978 and became effective on July 28, 1978 by Washington Administrative Order 78–10. The standard was not offered for **Federal Register** publication because of differences in the permissible exposure limit compared to the Federal standard. The State adopted an amendment to the DBCP standard on August 8, 1980, which became effective September 6, 1980 by Washington Administrative Order 80–14.

2. *Decision.* Having reviewed the State submission in comparison with the Federal standard, it has been determined that the State standard and the amendment are now identical to the comparable Federal standard and accordingly should be approved.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6003, Federal Office Building, 909 First Avenue, Seattle, Washington 97174; Department of Labor and Industries, General Administration Building, Olympia, Washington 98501; or the Office of State Programs, Room N–3613, 200 Constitution Avenue NW., Washington, D.C. 20210.

4. *Public Participation.* Under 29 CFR 1953.2(c) the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Washington State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are as effective as the Federal standards which were promulgated in accordance with Federal law including meeting requirements for public participation.

2. The standards were adopted in accordance with the procedural requirement of State law and further participation would be unnecessary.

This decision is effective June 22, 1982.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667)).

Signed at Seattle, Washington this 12th day of February, 1982.

John A. Granchi,

Acting Regional Administrator.

[FR Doc. 82–16742 Filed 6–21–82; 8:45 am]

BILLING CODE 4510–26–M

Washington State Standards; Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On January 26, 1973, notice was published in the **Federal Register** (38 FR 2421) of the approval of the Washington plan and the adoption of Subpart F to Part 1952 containing the decision.

The Washington plan provides for the adoption of Federal standards as State standards after public hearing. Sections 1952.120–124 of Subpart F set forth the State's schedule for the adoption of Federal standards. By letter dated November 19, 1980 from James P. Sullivan, Assistant Director, to James W. Lake, Regional Administrator, and incorporated as part of the plan, the State submitted an amendment to the State standard comparable to 29 CFR 1910.1002, Coal Tar Pitch Volatiles.

The Federal standard was published in the **Federal Register** (37 FR 24749) on November 21, 1972. The definition of coal tar pitch volatiles is contained in Chapter 296–62–020 WAC and was promulated pursuant to 34.04 RCW and of the Open Public Meetings Act of 1971, Chapter 42.30, on September 18, 1980. The State standard became effective December 12, 1980. The State standard adopts the language and definition of the interpretative rule that appeared in the **Federal Register**

2. *Decision.* Having reviewed the State submission in comparison with the Federal standard, it has been determined that the State standard is now identical to the comparable Federal standard and accordingly should be approved.

3. *Location of supplement for inspection and copying.* A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 6003, Federal Office Building, 909 First Avenue, Seattle, Washington 98174; Department of Labor and Industries, General Administration Building, Olympia, Washington 98501; and the Office of State Programs, Room N–3613, 200 Constitution Avenue NW., Washington, D.C. 20210.

4. *Public participation.* Under 29 CFR 1953.2(c) the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good causes exists for not publishing the supplement to the Washington State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standard is identical to the Federal standards which were promulgated in accordance with Federal law including meeting requirements for public participation.

2. The standard was adopted in accordance with the procedural requirements of State law and further participation would be necessary.

This decision is effective June 22, 1982.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667)).

Signed at Seattle, Washington this first day of March, 1982.

James W. Lake,

Regional Administrator.

[FR Doc. 82–16746 Filed 6–21–82; 8:45 am]

BILLING CODE 4510–26–M

Office of Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 82–98; Exemption Application No. D–2732]

Exemption From the Prohibitions for Certain Transactions Involving the Consolidated Steel & Supply Co., Employee Retirement Income Savings & Stock Investment Plan, Located in Elk Grove Village, Illinois

AGENCY: Department of Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption permits the sale of a parcel of real property (the Property) by the Consolidated Steel and Supply Co. Employee Retirement income Savings and Stock Investment plan (the Plan) to J and J Investment Company (J and J), a party in interest with respect to the Plan.

FOR FURTHER INFORMATION CONTACT: Louis Campagna of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216. (202) 523-8883. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On April 9, 1982, notice was published in the **Federal Register** (47 FR 15440) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1) (A) through (E) of the Code, for a transaction described in an application filed by J and J. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant represented that it has complied with the requirements of the notice to interested persons as stated in the notice of pendency. No public comments and no requests for a hearing were received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the sale of the Property by the Plan to J and J for the cash sum of $250,000, provided that this amount is not less than the fair market value of the Property at the time of sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 15th day of June, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 82-16731 Filed 6-21-82; 8:45 am]

BILLING CODE 4510-9-M

LIBRARY OF CONGRESS

Copyright Office

[Docket No. LPR 80-6]

Report of the Register of Copyrights on the Effects of 17 U.S.C. 108 on the Rights of Creators and the Needs of Users of Works Reproduced by Certain Libraries and Archives; Final Comment Period

AGENCY: Library of Congress, Copyright Office.

ACTION: Extension of final comment period.

The Copyright Office of the Library of Congress is preparing a report for Congress in accordance with 17 U.S.C. 108(i). The subject of the report is the extent to which 17 U.S.C. 108 has achieved the intended balance between the rights of creators and the needs of users of copyrighted works which are reproduced by certain libraries and archives. Five regional public hearings have been held to elicit views, comments, and information from all interested persons, including authors, copyright proprietors, libraries, and users of all types of libraries. On May 26, 1982, the Copyright Office published a final notice in 47 FR 23061 announcing that the Office requested final written comments by July 15, 1982 from organizations and individuals whose informed opinions may contribute to the preparation of that report.

The Office also announced the availability of, and invited written comment by July 15, 1982 on, the report of library photocopying prepared by King Research, Inc. under contract to the Library of Congress.

Supplementary information concerning the 17 U.S.C., section 108(i) report appeared in a prior notice at pages 79202 through 79204 of the **Federal**

Register for November 28, 1980 (45 FR, No. 231).

By letter of June 4, 1982, the American Library Association has requested a one-month extension of the comment period to allow full consultation within the library community before comments are submitted on the King Report. The delay, it is asserted, would enable all parties to analyze the King Report more carefully and lead to more thoughtful responses that would strenghten the Copyright Office report to Congress.

The Copyright Office has a statutory deadline of January 1, 1983 for submission of the report to Congress, and the magnitude of the task before us militates against any delay in receiving comments, if they are to be given full consideration by us. For this reason, the Office cannot accede fully to the request of the American Library Association. However, to facilitate the submission of informed views, the Office hereby announces an extension to August 2, 1982 of the final comment period concerning the 17 U.S.C. 108(i) report to Congress.

DATE: To become part of the record, and to be fully evaluated in preparing the report, all comments must be received by the Copyright Office on or before August 2, 1982.

ADDRESSES: Written comments should be submitted as follows:

If sent by mail:
Office of the General Counsel, Department D.S., Library of Congress, Washington, D.C. 20540.

If hand-delivered:
Office of the General Counsel, Madison Building, Room 407, First and Independence Avenue, S.E., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:
Dorothy Schrader, General Counsel, Department D.S., Library of Congress, Washington, D.C. 20540; Telephone: (202) 287–8380.

(17 U.S.C. 108)

Dated: June 10, 1982.

David Ladd,
Register of Copyrights.

Approved.

Daniel J. Boorstin,
The Librarian of Congress.

[FR Doc. 82-16840 Filed 6-21-82; 8:45 am]
BILLING CODE 1410-03-M

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

National Council on the Arts; Inter Arts Advisory Panel; Meeting

Pursuant to section 100a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Inter Arts Advisory Panel to the National Council on the Arts will be held on July 13, 1982, from 1:00 p.m.–5:30 p.m. in the 12th floor Screening Room and on July 14, 1982, from 9:00 a.m.–5:00 p.m. in room 1422 of the Columbia Plaza Office Complex, 2401 E Street, NW., Washington, D.C. 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6070.

John H. Clark,
Director, Office of Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 82-16769 Filed 6-21-82; 8:45 am]
BILLING CODE 7537-01-M

National Council on the Arts, Design Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the (Design Arts Advisory Panel (Design Exploration/ Research to the National Council on the Arts will be held on July 29, 1982, from 9:00 a.m.-6:00 p.m. in room 1422 of the Columbia Plaza Office Complex, 2401 E Street, N.W., Washington, D.C. 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections(c) (4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6070.

John H. Clark,
Director, Office of Council and Panel Operations, National Endowment for the Arts.

June 4, 1982.

[FR Doc. 82-16770 Filed 6-21-82; 8:45 am]
BILLING CODE 7537-01-M

NUCLEAR REGULATORY COMMISSION

[Byproduct Material License No. 34–13774–01; EA 81–72]

John C. Haynes Co.; Rescission of August 28, 1981; Order to Modify License

I

John C. Haynes Company, 800 Hebron Road, Heath, Ohio 43055 (the "licensee") is the holder of Byproduct Material License 34–13774–01 (the "license") issued by the Nuclear Regulatory Commission (the "Commission"). The license authorizes the possession and use of byproduct material under certain conditions specified therein. This license was originally issued on August 18, 1970. The license was due to expire on August 31, 1980; however, a timely renewal has been received.

II

As a result of the licensee's failure to make required payments to the Commission, the possibility that the licensee might lose physical control of its facility because of financial difficulties, and the failure to complete a radiation survey and decontamination report, an Order to Modify License No. 34–13774–01 was issued on August 28, 1981.

III

As of September 9, 1981 all required payments were made to the Commission by the licensee. By letter dated April 2, 1982, the licensee submitted to the Commission a copy of the paid mortage on his property and stated that he had received complete ownership of the property. On April 26, 1982 the license was amended to restrict possession of radioactive material to storage only, until final action is taken on the renewal application.

IV

In view of the foregoing, the August 28 Order to Modify License is hereby rescinded.

Effective Date: June 15, 1982, Bethesda, Maryland.

For the Nuclear Regulatory Commission.

Richard C. DeYoung,

Director, Office of Inspection and Enforcement.

[FR Doc. 82-16820 Filed 6-21-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-416]

Mississippi Power & Light Co., Middle South Energy, Inc., South Mississippi Electric Power Association, and Grand Gulf Nuclear Station, Unit No. 1; Issuance of Facility Operating License.

Notice is hereby given that the Nuclear Regulatory Commission (the Commission), has issued Facility Operating License No. NPF-13 to Mississippi Power & Light Company, Middle South Energy, Inc., and South Mississippi Electric Power Association (the licensees) which authorizes operation of the Grand Gulf Nuclear Station, Unit 1 (the facility) by Mississippi Power & Light Company at reactor core power levels not in excess of 191 megawatts thermal (5 percent power) in accordance with the provisions of the License, the Technical Specifications and the Environmental Protection Plan.

Grand Gulf Nuclear Station, Unit 1 is a boiling water nuclear reactor located at the licensees' site in Claiborne County, Mississippi. The license is effective as of the date of issuance and shall expire at midnight on September 4, 2014.

The application for the license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulation. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which are set forth in the license. Prior public notice of the overall action involving the proposed issuance of an operating license was published in the **Federal Register** on July 28, 1978 (43 FR 32903-32904).

The Commission has determined that the issuance of this license will not result in any environmental impacts other than those evaluated in the Final Environmental Statement since the activity authorized by the license is encompassed by the overall action evaluated in the Final Environmental Statement.

For further details with respect to this action, see (1) Facility Operating License No. NPF-13, complete with Technical Specifications and Environmental Protection Plan; (2) the report of the Advisory Committee on Reactor Safeguards dated October 20, 1981; (3) the Commission's Safety Evaluation Report dated September 1981, Supplement No. 1 dated December 1981, and Supplement No. 2 dated June 1982; (4) the Final Safety Analysis Report and amendments thereto; (5) the Environmental Report and Supplements thereto; and (6) the Final Environmental Statement dated September 1981.

These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555, and at the Hinds Jr. College, George M. McLendon Library, Raymond, Mississippi 39154. A copy of Facility Operating License No. NPF-13 may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Attention: Director, Division of Licensing. Copies of the Safety Evaluation Report and its Supplements No. 1 and No. 2 (NUREG-0831) may be purchased at current rates from the National Technical Information Service, Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161, and through the NRC GPO sales program by writing to the U.S. Nuclear Regulatory Commission, Attention: Sales Manager, Washington, D.C. 20555. GPO deposit account holders can call 301-492-9530.

Dated at Bethesda, Maryland, this 16th day of June 1982.

For the Nuclear Regulatory Commission.

A. Schwencer,

Chief, Licensing Branch No. 2, Division of Licensing.

[FR Doc. 82-16815 Filed 6-21-82; 8:45 am]

BILLING CODE 7590-01-M

[License: 42-16559-01, EA 82-27]

Nuclear Energy Services, Inc.; Order Imposing Civil Monetary Penalties

I

Nuclear Energy Services, Inc., Conam Insection Division, 6106 Rookin Street, Houston, Texas (the "licensee") is the holder of License 42-16559-01 (the "license") issued by the Nuclear Regulatory Commission (the "Commission"). License 42-16559-01 authorizes the use of sealed sources of byproduct material.

II

An investigation of the licensee's activities under the license was conducted intermittently during the period October 15 to November 3, 1981. In addition, at licensee's facility located in Folcroft, Pennsylvania an inspection was conducted intermittently during the period July 23 to October 15, 1981. As a result of the investigation and inspection, it appears that the licensee had not conducted its activities in full compliance with the requirements of NRC regulations. A written Notice of Violation and Proposed Imposition of Civil Penalties was served upon the licensee by letter dated March 16, 1982. This Notice stated the nature of the violations, the provisions of the Nuclear Regulatory Commission regulations which the licensee had violated, and the amount of civil penalties proposed for each violation. An answer dated April 14, 1982 to the Notice of Violation and Proposed Imposition of Civil Penalties was received from the licensee.

III

Upon consideration of the answers received and the statements of fact, explanation, and argument for mitigation or cancellation contained therein, as set forth in the enclosure to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for the violations designated in the Notice of Violation and Proposed Imposition of Civil Penalties should be imposed.

In view of the foregoing and pursuant to section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282, Pub. L. 96-295) and 10 CFR 2.205, it is hereby ordered that:

The licensee pay civil penalties in the total amount of Nine Thousand Dollars within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States, and mailed to the Director of the Office of Inspection and Enforcement.

IV

The licensee may, within 30 days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A copy of the hearing request shall also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of hearing. Upon failure of the licensee to request a hearing within 30 days of the date, of this Order, the provisions of this Order shall be effective without further

proceeding and, if payment has not been made by that time, the matter may be referred to the Attorney General for collection.

V

In the event the licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the licensee violated NRC regulations as set forth in the Notice of Violation and Proposed Imposition of Civil Penalties, as amended; and,

(b) Whether, on the basis of such violations, this Order should be sustained.

Dated at Bethesda, Maryland, this 14th day of June 1982.

For The Nuclear Regulatory Commission.

Richard C. DeYoung,

Director, Office of Inspection and Enforcement.

Appendix—Evaluations and Conclusions

For each violation and associated civil penalty identified in the Notice of Violation (dated March 16, 1982) the original violation is restated and the Office of Inspection and Enforcement evaluation and conclusion regarding the licensee's response (dated April 14, 1982) to each item is presented.

Item 1A

Statement of Violation. 10 CFR 34.31(a) requires that radiographers be trained in specified subjects and demonstrate an understanding of these subjects as well as competence in the use of radiography equipment.

Contrary to the above, the licensee permitted an individual without the required training, and prior to a demonstration of competence in the use of radiography equipment, to perform radiography at a field site in Mahwah, New Jersey, on July 25, 1980.

This is a Severity Level III violation (Supplement VII). (Civil Penalty—$5,000).

Evaluation and Conclusion. The licensee admits that an individual without the required training, and prior to a demonstration of competence in the use of radiography equipment, was permitted to perform radiography at a field site in Mahwah, New Jersey, on July 25, 1980. The licensee requested mitigation of proposed civil penalty on the following grounds:

1. Conam's own investigation did not establish prior knowledge by the Folcroft manager about the violation.

2. Conam's president and the individual to whom he reports cannot recall, in the 15 years they have been with the Company, a single incident where the management of Conam has been accused of coaching an employee to cover up an incident, withholding information from the Commission, discouraging employees from contacting the Commission, backdating records, or otherwise being anything but honest with the Commission.

Violations by a licensee's employee of NRC regulations are chargeable to the licensee himself regardless of management involvement. In the case in question, moreover, the results of the investigation and inspection indicate that the violation occurred with the knowledge of the Folcroft manager. Consequently, the licensee's response to Item 1A provides insufficient basis for mitigation of the proposed penalty. Accordingly, the Civil Penalty remains at Five Thousand Dollars.

Item 1 B

Statement of Violation. 10 CFR 34.22(a) requires, in part, that during radiographic operations the sealed source assembly be secured in the shielded position each time the source is returned to that position. 10 CFR 34.43(b) requires that a physical radiation survey be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position.

Contrary to the above, on June 9, 1981, the sealed source assembly had not been secured in the shielded position nor had a physical radiation survey been made to determine that the source had been returned to its shielded position after a radiographic exposure. This contributed to a radiographer's receiving a radiation dose of about one rem.

This is a Severity Level III violation (Supplement IV) (Civil Penalty—$2,000).

Evaluation and Conclusion. The licensee admits that on June 9, 1981 the sealed source assembly had not been secured in the shielded position nor had a physical radiation survey been made to determine that the source had been returned to its shielded position after a radiographic exposure. This contributed to a radiographer's receiving a radiation dose of about one rem. The licensee requested remission of the Civil Penalty on the following grounds:

Fines should not be assessed because historically the Commission has not assessed a penalty with respect to licensee identified and documented incidents not resulting in overexposures.

The licensee's statement is not in accord with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982) or the Interim Enforcement Policy, 45 FR 66756 (October 7, 1980). Under both policies in Supplement IV, paragraph C.4, a Severity Level III violation is indicated where there is a substantial potential for an exposure exceeding regulatory limits. The incident in question had such a potential. Under both policies a civil penalty is usually imposed for Severity Level III violations.

It is also true that under both policies up to a 50 percent reduction of the base level penalty may be considered for violations which the licensee has identified and promptly reported. In this case, a 50 percent reduction has already been considered and granted, since the base amount of the penalty under both policies is $4,000.

Consequently, the licensee's response above provides insufficient basis for mitigation of the proposed penalty. Accordingly, the Civil Penalty remains at Two Thousand Dollars.

Item 1C

Statement of Violation. 10 CFR 34.41 requires, in part, that during each radiographic operation, the radiographer or radiographer's assistant maintains direct surveillance of the operation to protect against unauthorized entry into a high radiation area.

Contrary to the above, the licensee failed to maintain direct surveillance over a radiographic operation on October 4, 1980, at a field site in Ridgewood, New Jersey, and allowed a member of the general public to enter a high radiation area.

This is a Severity level III violation (Supplement VII) (Civil Penalty $2,000).

Evaluation and Conclusion. The licensee admits that its radiographer did not maintain direct surveillance over a radiographic operation on October 14, 1980, at a field site in Ridgewood, New Jersey, and allowed a member of the public to enter a high radiation area. The licensee requested remission of proposed civil penalty on the same grounds as stated in Item 1B. Consequently, the licensee's response provides the same insufficient basis for remission of the proposed penalty. Accordingly, the Civil Penalty remains at Two Thousand Dollars.

[FR Doc. 82-16819 Filed 6-21-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-275 and 323]

Pacific Gas & Electric Co. (Diablo Canyon Nuclear Power Plant, Units 1 and 2); Receipt of Petition Under 10 CFR 2.206

Notice is hereby given that by petitions dated May 12 and 25, 1982, Mr. Joel Reynolds on behalf of the Joint Intervenors to the Diablo Canyon Nuclear Power Plant licensing proceedings, filed a request for issuance of an order to Pacific Gas & Electric Co. to show cause why it should not be required to submit an amendment to its operating license applications to reflect recent changes in the organization and management of the Diablo Canyon project. In accordance with the procedures specified in 10 CFR 2.206, appropriate action will be taken on this request within a reasonable time.

A copy of the request is available for inspection in the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555 and at the local public document room for the Diablo Canyon plant at the San Luis Obispo County Free Library, 888 Morro Street, San Luis Obispo, California 93406.

Dated at Bethesda, Maryland, this 16 day of June, 1982.

For the Nuclear Regulatory Commission.

Harold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 82-16816 Filed 6-21-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-513 and 50-509]

Washington Public Power Supply System, Washington Nuclear Project Nos. 4 and 5; Issuance of Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has denied two petitions under 10 CFR 2.206 filed by the Coalition for Safe Power of Portland, Oregon. The petitions asked that the Director revoke the construction permit for WNP No. 4 on the basis of a material false statement in an application for extension of the permit and revoke the permits for WNP No. 4 and WNP No. 5 in view of the Washington Public Power Supply System's recent termination of its participation in the two projects. The petitions have been denied because no material false statement was made in the extension application and because no compelling reason exists at this time for revoking the permits.

The reasons for this denial are fully described in a "Director's Decision Under 10 CFR 2.206" which is available for public inspection in the NRC's public document rooms at 1717 H Street, N.W., Washington, D.C. 20555, the Richland Public Library, Swift & Northgate Streets, Richland, WA 99352, and the W. H. Abel Memorial Library, 125 Main Street, South, Montesano, WA 98563. A copy of the decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR 2.206(c).

Dated at Bethesda, Maryland, this 16th day of June 1982.

For the Nuclear Regulatory Commission.

Harold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 82-16817 Filed 6-21-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-509, 50-513]

Washington Public Power Supply System (WNP Nos. 4 & 5); Director's Decision Under 10 CFR 2.206

Nina Bell, on behalf of the Coalition for Safe Power, Portland, Oregon, has filed two petitions under 10 CFR 2.206 that request certain actions with respect to two nuclear projects for which the Washington Public Power Supply System (WPPSS) holds construction permits. In its petition dated November 30, 1981, the Coalition requested that the Director of Nuclear Reactor Regulation issue an order to show cause why the construction permit for WPPSS Nuclear Project (WNP) No. 4 should not be revoked on the basis of an alleged "material false statement" in WPPSS' July 1981 application for an extension of the WNP No. 4 construction permit. The Coalition has filed another petition, dated March 16, 1982, under 10 CFR 2.206 which requests that WPPSS be ordered to show cause why the construction permits for WNP Nos. 4 and 5 should not be revoked, because WPPSS has announced its intention to terminate its participation in the two projects. For the reasons set forth in this decision, the Coalition's petitions are denied.

I. WPPSS Did Not Make a "Material False Statement" in its Application for Extension of the WNP No. 4 Permit

On July 21, 1981, WPPSS submitted an application for extension of the latest completion dates for construction of WNP No. 1 and WNP No. 4.[1] WPPSS assigned the following reasons as bases for extending the permits: "Subsequent to the issuance of the construction permits delays in the construction of WNP-1 and WNP-4 have occurred. The primary factors causing these delays are as follows:

1. Changes in the scope of the projects including increases in the amount of material and engineering required as a result of regulatory actions, in particular those subsequent to the TMI-2 accident.

2. Construction delays and lower than estimated productivity which resulted in delays in installation of material and equipment and delays in completion of systems necessitating rescheduling of preoperational testing.

3. Strikes by portions of the construction work force.

4. Changes in plant design.

5. Delays in delivery of equipment and materials."[2]

On October 26, 1981, WPPSS formally advised the staff that the WPPSS Board of Directors had voted to defer further construction of WNP Nos. 4 and 5 until June 30 1983, "because of difficulties in simultaneous financing of all five of our plants now under construction, given the current high interest rates and bond market conditions."[3] WPPSS subsequently withdrew its July 21, 1981, application insofar as it requested an extension of the WNP No. 4 construction permit in view of its deferral of the project's construction.[4]

The Coalition claims that WPPSS made a material false statement in its July 21st application because WPPSS omitted any mention of cash flow difficulties affecting the completion date of WNP-4. The Coalition points to a study prepared for WPPSS that examined options to slow the pace of construction on WNP Nos. 4 and 5 as a way to reduce the burden of near-term funding requirements. *See* WPPSS, *Alternative Evaluations—WNP 4/5* (March 26, 1981) (Attachment A to Coalition petition). The Coalition also notes that the WPPSS Managing Director proposed a one-year moratorium on construction of WNP Nos. 4 and 5 in May 1981 to the WPPSS Board of Directors as a way of easing WPPSS' immediate financial burdens.

The moratorium would also provide an opportunity to re-examine WPPSS' need to build the two projects. *See* Speech of Robert Ferguson, 1 *Power Lines* (WPPSS newsletter) at 3-6 (June 12, 1981) (Attachment B to Coalition petition). The WPPSS Board of Directors approved the one-year moratorium on construction. *See* Coalition Petition at 3 (Nov. 30, 1981). The Coalition charges that, by omitting any reference to the foregoing facts, WPPSS made a material false statement, because these facts indicate "cash flow difficulties" affecting the completion date for WNP No. 4. Consequently, the Coalition urges the construction permit for WNP No. 4 should be revoked for this alleged offense.

Although the Coalition's petition might otherwise be considered moot because WPPSS has withdrawn the extension application for WNP No. 4, the substance of the Coalition's petition should be addressed to dispel the notion that WPPSS committed the alleged violation. Moreover, withdrawal of the application would not in itself absolve WPPSS of reponsibility for a material false statement had one been made. Under the circumstances here, WPPSS did not make a material false statement.

The Commission's authority to take enforcement action for material false statements derives from section 186 of the Atomic Energy Act of 1954, as amended:

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[1] The application consists of a three page letter from G. D. Bouchey, WPPSS Director of Nuclear Safety, to H. R. Denton, Director of NRR, and an affidavit signed by Mr. Bouchey. *See* Attachment C to the Coalition's Petition (Nov. 31, 1981). With respect to WNP No. 1, the application requests an extension of the latest completion date under Construction Permit No. CPPR-134 from January 1, 1982, to June 1, 1986. The application requests an extension of the latest completion date for WNP No. 4 under Construction Permit No. CPPR-174 from December 1, 1985, to June 1, 1987.

[2] Letter from G. D. Bouchey, at 1-2.

[3] Letter from R. L. Ferguson, WPPSS Managing Director, to H. R. Denton, Director of NRR (Oct. 26, 1981).

[4] Letter from J. W. Shannon, WPPSS Director of Safety & Security, to H. R. Denton, Director of NRR (Dec. 31, 1981). WPPSS indicated in this letter than it might reapply for the extension of the WNP No. 4 permit after June 1983. WPPSS has since announced termination of the project. *See* note 10 *infra*.

Any license may be revoked for any material false statement in the application or any statement of fact required under section 182, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Commission to refuse to grant a license on an original application * * *" 42 U.S.C. 2236(a).

The Commission addressed the meaning of the term "material false statement" in its decision in *Virginia Electric & Power Co.*, (North Anna Power Station, Units 1 and 2), CLI-76-22, 4 NRC 480 (1976), *aff'd*, 571 F.2d 1289 (4th Cir. 1978) (hereinafter VEPCO). In *VEPCO*, the Commission determined that material false statements excompass material omissions. 4 NRC at 489-91. Knowledge of falsity is not necessary for liability for a material false statement. 4 NRC at 486. With respect to the materiality of an omission, the Commission stated:

By reading material false statements to encompass omissions of material data, we do not suggest that unless all information, however trivial, is forwarded to the agency the applicant will be subject to civil penalties. An omission must be material to the licensing process to bring section 186 into play * * * [D]eterminations of materiality require careful, common-sense judgments of the context in which information appears and the stage of the licensing process involved. Materiality depends upon whether information has a natural tendency or capability to influence a reasonable agency expert.

4 NRC at 491.

In the context of an application for extension of a construction permit, WPPSS' omission of a specific reference to its financial burdens and its planned delay of construction to ease those burdens did not constitute a material omission.

No specific form of application is required, but the Commission's regulations indicate that good cause for extension of a permit cause may be shown by pleading:

"among other things, developmental problems attributable to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, and act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

CFR 50.55(b).

No particular analysis or detailed evaluation of the reasons supporting an extension is specified, though, of course, the applicant risks denial of the application if the showing of cause is stated too summarily or excludes mention of additional reasons that would warrant extension.

In this instance, WPPSS briefly stated several common reasons contributing to delays in completion of WNP Nos. 1 and 4. Although WPPSS did not specifically mention financial considerations as a cause of delays in construction of WNP No. 4, WPPSS lists "construction delays" as one of the "primary factors" that casued its inability to meet the completion date and that would thereby justify an extension. Given the general state of the nuclear industry, the staff would consider "construction delays" to include delays caused by, or planned to alleviate, financial constraints. The staff has considered a number of extension applications in the past few years that have attributed delays in construction to economic conditions or financial considerations. *See* note 7 *infra*. The staff was generally aware that WPPSS was facing significant burdens in attempting to finance construction of its five nuclear projects. The financial strain and the decision by the WPPSS Board of Directors in June 1981 to slow construction of WNP Nos. 4 and 5 were reported in the trade press.[5]

Financial considerations leading to a planned reduction in construction activity do not pose in themselves a *safety* issue that would have tended to cause the staff to look at WPPSS' application for extension in a different light.[6] Moreover, the planned delay due to financial considerations could well have been an acceptable justification for the requested extension. Extension applications have been granted in the past when applicants have requested extension of the facility completion date on the basis of financial constraints that slowed construction schedules.[7]

This was not an instance in which, after the filing of the application, the staff had requested information about or had expressed in interest in a certain subject matter concerning the application and the applicant had failed to fully and accurately respond to the staff's request for information. And, it should be noted, the staff was informed of developments regarding construction of WNP No. 4 after WPPSS tendered the application in July 1981.[8] In view of the general state of the industry and the particular circumstances surrounding WPPSS application, the staff was not mislead by omission of a specific reference to financial constraints in the extension application. The staff does not find that WPPSS should be charged with making a "material false statement" in its July 21st application. The Coalition's petition dated November 30, 1981 is *denied*.[9]

II. No Compelling Reasons Warrant Revocation of the Permits for WNP Nos. 4 and 5

The Coalition's latest petition, dated March 16, 1982, requests that WPPSS be ordered to show cause why the construction permits for WNP Nos. 4 and 5 should not be revoked on the basis of the WPPSS Board of Directors' adoption of a resolution terminating the projects. In these particular circumstances, an order is not warranted, and, therefore, the Coalition's petition is denied.

The WPPSS Board of Directors adopted the resolution terminating the projects on January 22, 1982, and soon thereafter WPPSS informed the Executive Director for Operations of its intention to conduct a two-phase plan for termination.[10] Initially, WPPSS intends to attempt to sell the plants to a new owner. If WPPSS finds that it is unlikely that the projects can be sold in their entirety, WPPSS may attempt to sell plant equipment and materials in

[5] *See, e.g., WPPSS Construction Bonds Were Downgraded Only A Bit by Standard & Poor's*, 22 Nucleonics Week No. 25, at 9-10 (June 25, 1981); *Last Week's Downgrading of WPPSS Construction Bonds*, 22 Nculeonics Week No. 24, at 12 (June 18, 1981).

[6] *Cf. Elimination of Review of Financial Qualifications of Electric Utilities in Licensing Hearings for Nuclear Power Plants*, 47 FR 13750, 13751 (March 31, 1982).

[7] *See, e.g., Orders Extending Construction Completions Dates*, 46 FR 62989 (Dec. 29, 1981) (Callaway plant); 46 FR 56264 (Nov. 16, 1981) (Waterford Station); 46 FR 46032 (Sept. 16, 1981) (Hope Creek Station); 46 FR 29804 (June 3, 1981) (Limerick Station); 44 FR 29547 (May 21, 1979) (North Anna Station).

[8] The NRR project manager was informed by telephone in August 1981 that WPPSS was considering more extensive deferrals of construction on WNP No. 4, and generally kept himself appraised of the situation via telephone calls, media reports and site visits (for other reasons) in September and October 1981. On the basis of the uncertainties surrounding WNP No. 4's future, NRR had not initiated any review of the extension application. After the WPPSS Board approved deferral of construction of WNP Nos. 4 and 5 until June 30, 1983, WPPSS informed NRR of the construction deferral *See supra* note 3. Eventually, WPPSS withdrew the extension application. *See supra* note 4.

[9] Even if the omission had been found to be a "material false statement", permit revocation would not necessarily follow. Although section 186 of the Atomic Energy Act authorizes revocation for material false statements, it does *not* compel revocation. Rather, the Commission is empowered to impose the remedy it deems fit for the gravity of the offense, and could impose enforcement sanctions ranging from a notice of violation (10 CFR 2.201) to civil penalties (10 CFR 2.205) to appropriate orders (10 CFR 2.202 and 2.204). Any attempted suspension or revocation of the permit would also be subject to the second chance doctrine of section 9(b) of the Administrative Procedure Act. 5 U.S.C. 558(c); *see also* Atomic Energy Act section 186b. 42 U.S.C. 2236(b).

[10] *See* Letter from R. L. Ferguson, WPPSS Managing Director, to W. J. Dircks, EDO (Feb. 1, 1982) (Attachment B to Coalition petition dated March 16, 1982).

some other manner. WPPSS intends to retain the construction permits at least during the first phase of its termination plan that calls for an attempted transfer of the projects to a new owner. The construction permits for WNP Nos. 4 and 5 would otherwise expire by their own terms in 1985 and 1986 respectively.

The Coalition's petition is based on WPPSS' intended termination of the project owing to financial considerations. However, termination of the projects does not itself pose any hazard to public health and safety that would require issuance of an order to show cause.[11] Although the NRC has no interest in seeing that WPPSS salvages a portion of its investment in the projects, there is no reason for the NRC to obstruct WPPSS' efforts when public health and safety is not affected by WPPSS' actions.[12]

The staff recognizes that a similar petition under 10 CFR 2.206 has been granted on one occasion. *See Northern States Power Co.* (Tyrone Energy Park, Unit 1), CLI–80–36, 12 NRC 523 (1980).[13] The staff's action in that instance does not compel, however, the same result here. In *Tyrone*, the co-owners of the project announced no specific plans to find another owner of the project and indicated no desire to retain the construction permit.[14] Moreover, the co-owners consented to revocation of the Tyrone permit. *See Order Revoking Construction Permit*, 46 FR 11746 (Feb. 10, 1981). The circumstances surrounding the termination of WPPSS' participation in WNP Nos. 4 and 5 are different. WPPSS wants to retain the permits in the hope that it may be able to transfer the projects to a new owner. Such action, subject to Commission approval, is lawful, and WPPSS' plans to preserve the present status of the plants appear reasonable.[15] The issuance of an order to show cause is not required in these circumstances to abate some hazard to public health and safety. Although formal termination of the permits may be appropriate at some future date, no compelling reason exists to take such a step at this time.

III. Conclusion

WPPSS made no material false statement in its application for extension of the WNP No. 4. No substantial health and safety issue warrants issuance of an order to show cause. For these basic reasons, the Coalition for Safe Power's petitions dated November 30, 1981, and March 16, 1982 are *denied*. As provided in 10 CFR 2.206(c), a copy of this decision will be filed with the Secretary for the Commission's review.

Dated at Bethesda, Maryland this 16th day of June, 1982.

Harold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 82–16818 Filed 6–21–82; 8:45 am]

BILLING CODE 7590–01–M

[11] *See Northern Indiana Public Service Co.* (Bailly Generating Station, Nuclear-1), CLI–78–7, 7 NRC 429, 433 (1978), *aff'd sub nom. Porter County Chap. of the Izaak Walton League, Inc. v. NRC*, 606 F.2d 1363 (D.C. Cir. 1979). In the recent statement of consideration concerning the *Elimination of Review of Financial Qualifications of Electric Utilities in Licensing Hearings for Nuclear Power Plants*, 47 FR 13750, 13751 (March 31, 1982), the Commission noted, "WPPSS' response (and that of most other utilities encountering financial difficulties) has been to postpone or cancel their plants, actions clearly not inimical to public health and safety under the Atomic Energy Act."

[12] Of course, any transfer of the construction permits would require the Commission's approval. *See* Atomic Energy Act section 184, 42 U.S.C. 2234, 10 CFR 50.54(c) and 50.80.

[13] The *Order to Show Cause* was published at 45 FR 42093 (June 23, 1980); the *Order Revoking Construction Permit* was published at 46 FR 11746 (Feb. 10, 1981).

[14] The permittees' cancellation of the Tyrone project was based largely on the Wisconsin Public Service Commission's denial of the necessary state certificate to construct the facility.

[15] *See* letter from R. L. Tedesco, Ass't Director for Licensing, Division of Licensing, NRR, to R. L. Ferguson, WPPSS Managing Director (Attachment C to Coalition petition dated March 16, 1982).

PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

Meeting

Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committees Act, that the twenty-second meeting of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research will be held in the Auditorium of The Medical Society of the District of Columbia, 2007 Eye Street, N.W., Washington, D.C. from 9 a.m. to 5 p.m. on Friday, July 9, 1982 and from 8:30 a.m. to 3:30 p.m. on Saturday, July 10, 1982.

The meeting will be open to the public, subject to limitations of available space. The agenda for Friday, July 9 will include, among other things, discussion of a draft report on the ethical implications of differences in the availability of health services. The agenda for Saturday, July 10 will include, among other things, discussion of a draft report on the ethical and social implications of gene splicing in human beings.

During Friday afternoon at approximately 1:15 p.m., and Saturday afternoon, at approximately 1 p.m., fifteen minutes will be devoted to comments from the floor on the subject of any of the agenda items, limited to three minutes per comment. Written suggestions and comments will be accepted for the record from those who are unable to speak because of the constraints of time and from those unable to attend the meeting.

Records shall be kept on all Commission proceedings and will be available for public inspection at the Commission office, located in Suite 555, 2000 K Street, NW., Washington, D.C. 20006.

For further information, contact Andrew Burness, Public Information Officer, at (202) 653–8051.

Alexander M. Capron,

Executive Director.

[FR Doc. 82–16046 Filed 6–21–82; 8:45 am]

BILLING CODE 6820–AV–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. 12493; 812–5193]

American General Life Insurance Co. of Delaware, et al.; Application

June 15, 1982.

Notice is hereby given that American General Life Insurance Company of Delaware (the "Company"), a Delaware stock life insurance company, American General Life Insurance Company of Delaware Separate Account D (the "Separate Account"), a separate account registered under the Investment Company Act of 1940 (the "Act") as a unit investment trust, and American General Capital Distributors, Inc. ("Distributors"), 2727 Allen Parkway, Houston, Texas 77001, the principal underwriter for the Separate Account (collectively, "Applicants"), filed an application on May 26, 1982 and an amendment thereto on June 10, 1982, for an order of exemption, pursuant to section 6(c) of the Act, from sections 26(a), 26(a)(2)(D), and 27(c)(2) and for an order approving certain offers of exchange pursuant to section 11 of the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Introduction

The Separate Account funds certain variable annuity contracts currently being offered and sold by the Company (the "Current Contracts"). Subject to certain conditions, owners of the Current Contracts may, from time to

time, cause their interests in the Separate Account to be allocated for investment purposes among several of the seven divisions of the Separate Account, each of which invests its assets solely in a different open-end management investment company registered under the Act (a "Fund"). At the present time, the only divisions available for use under the Current Contracts during both the accumulation and annuity periods are divisions six and seven, and Applicants have previously applied for and received Commission approval under section 11 of the Act with respect to transfers between such divisions pursuant to the Current Contracts. The Company proposes to add division eight to provide another investment option to contract holders, as originally contemplated by the Current Contract.

The Separate Account also funds certain variable annuity contracts previously sold upon which only additional puruchase payments are now being accepted ("Original Contracts"). Original Contract owners may now have additional purchase payments invested in divisions one through seven. The Company proposes to add division eight to permit another investment option for Original Contract owners and to allow transfers among all the eligible divisions. The Company states that it will advise Original Contract owners affected by Revenue Ruling 81–225 of the possible advantages of limiting their use of the Separate Account to divisions six, seven and eight.

Exemptions From Trustee and Custodian Requirements

Section 27(c)(2) of the Act prohibits a registered investment company or any depositor or underwriter for such Company from selling periodic payment plan certificates, unless the proceeds of all payments other than the sales load are deposited with a trustee or custodian having the qualifications prescribed in section 26(a)(1) and held under an agreement containing, in substance, the provisions required by sections 26(a) (2) and (3) of the Act. Section 26(a)(2)(D) of the Act requires, in part, that under the agreement with the trustee or custodian, such entity must have possession of all the securities and other property in which funds of a unit investment trust are invested. This has been interpreted to mean that the securities owned by the trust must be represented by share certificates physically in the custody of the custodian. Each of the Funds, however, maintains an "open account" system, and certificates for shares of the Funds will not be issued to the Company in connection with share purchases by the Separate Account.

Applicants request exemptions from sections 26(a), 26(a)(2)(D) and 27(c)(2) of the Act in order that assets of the Separate Account may be held by the Company under the terms and conditions set forth in the application. In support of these requested exemptions, Applicants state that except for fund shares, the Separate Account's only assets will consist of small amounts of cash from time to time. Such cash will be kept on deposit in the name of the Separate Account with a bank meeting the requirements of section 26(a)(1) of the Act.

According to Applicants, safekeeping of Separate Account assets does not require the Fund certificates be issued to the Company and any such requirement would, in fact, result in unnecessary administrative expenses. The application states that all obligations under the Company's variable annuity contracts will be general obligations of the Company which may not be abrogated, and the assets and retained earnings of the Company provide ample assurance of its financial ability to meet its obligations under such contracts. According to the application, the Company is subject to extensive supervision and control by the insurance regulatory authorities of the State of Delaware and of each other state in which it does business.

Approvals Under Section 11

Section 11(a) of the Act, in effect, requires that the terms of any offer made to a security holder of an open-end investment company registered under the Act to exchange his or her security for the security of the same or another open-end investment company registered under the Act must receive prior Commission approval, if the exchange is to be made on a basis other than the relative net asset values of the interests to be exchanged. Section 11(c) provides that, irrespective of the basis of exchange, the provisions of section 11(a) shall be applicable, in part, to any offer of exchange of any securities of registered unit investment trusts.

Applicants state that sections 11(a) or 11(c) of the Act could be interpreted to require Commission approval of transfers among divisions of the Separate Account pursuant to the Current Contracts. Although Applicants do not necessarily agree that any such interpretation would be correct, Applicants request Commission approval under those sections to the extent necessary to permit Current Contract owners and beneficiaries to effect transfers among the various divisions of the Separate Account, including division eight, subject to an administrative charge of $10 per transfer and to effect transfers among various divisions of the Separate Account, including division eight, pursuant to the Original Contracts. Applicants state that shares of the Funds purchased and sold for the various divisions of the Separate Account are in all cases purchased and sold at net asset value, with no sales or withdrawal charge being imposed.

According to the application, transfers among divisions of the Separate Account are intended primarily to permit a contract owner to modify a previous allocation in light of changing personal needs and evolving economic conditions, and such transfer do not generate any increased revenues or fees to the Company or its affiliates.

Section 6(c)

Section 6(c) of the Act, in pertinent part, provides that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes or persons, securities, or transactions, from any provision or provisions of the Act to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, no later than July 6, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his or her interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he or she may request that he or she be notified if the Commission shall order a hearing thereon. Any such communciations should be addressed: Secretary, Securities and Exchange Commission, Washinton, D.C. 20549. A copy of such request shall be served personally or by mail upon the Applicants at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following July 6, 1982, unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or

advice as to whether a hearing is ordered, will receive any notice and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-16807 Filed 6-21-82: 8:45 am]

BILLING CODE 8010-01-M

[Rel. No. 12494; 812-5201]

Variable Annuity Life Insurance Co., et al.; Application

June 15, 1982

Notice is hereby given that The Variable Annuity Life Insurance Company ("VALIC"), The Variable Annuity Life Insurance Company Separate Account A ("Account A"), and The Variable Annuity Marketing Company ("VAMCO") (collectively, "Applicants"), 2727 Allen Parkway, Houston, Texas 77019, filed an application on June 1, 1982, for an order of the Commission pursuant to section 6(c) of the Investment Company Act of 1940 ("Act") exempting Applicants to the extent requested, from sections 26(a)(2)(D) and 27(c)(2) of the Act and pursuant to section 11 of the Act, approving certain offers of exchange. VALIC is a Texas stock life insurance company; Account A, a separate account of VALIC, is registered under the Act as a unit investment trust. VALIC is the depositor of, and VAMCO, the principal underwriter for, Account A. All interested persons are referred to the application on file with the Commission for a statement of the representations made therein, which are summarized below.

Account A funds variable annuity contracts (the "Contracts") issued by VAIIC. The Contracts are individual variable annuity contracts designed to establish retirement benefits under certain programs providing federal tax advantages. Net purchase payments (the amount of a purchase payment less applicable premium taxes) with respect to the Contracts may be placed in Account A and allocated to one or more of its divisions or allocated to VALIC's general account. The assets of each division of Account A are invested solely in shares of an open-end management investment company (a "Fund"). Divisions One and Two of Account A presently used in connection with the Contracts are invested in High Yield Accumulation Fund, Inc. and American General Money Market Fund, Inc. Applicants are planning to add a Division Three which shall invest in American General Equity Accumulation Fund, Inc., regarding which the present application is being made. During the accumulation and annuity periods, the terms of the Contracts permit contractowners and, in certain cases, beneficiaries under the Contracts to make transfers between the divisions of Account A or among the divisions and VALIC's general account, subject to certain limitations. Transfers will be effected at net asset value and no transfer charge will be imposed. The privilege of making transfers during the accumulation and annuity period may be suspended or terminated by VALIC at any time.

Applicants have previously obtained an exemption from various sections of the Act, including sections 26(a)(2)(D) and 27(c)(2), relating to possession of Account A's assets, and an order under section 11 of the Act approving certain offers of exchange in connection with transfers between Divisions One and Two. Applicants assert that the terms of such exemption and approval are in all respects sufficiently broad to include the addition of proposed Division Three. Nevertheless, Applicants have been advised by the staff of the Commission that the addition of a new division will, in the staffs vien, require an order of the Commission, pursuant to Section 11 of the Act approving certain offers of exchange and pursuant to section 6(c) of the Act for exemptions from sections 26(a)(2)(D) and 27(c)(2) of the Act with respect to newly created Division Three.

Exemptions Relating To Custodial Requirements

Section 27(c)(2) of the Act prohibits a registered investment company or any depositor or underwriter for such company from selling periodic payment plan certificates, unless the proceeds of all payments other than the sales load are deposited with a trustee or custodian having the qualifications prescribed in section 26(a)(1) of the Act and held under an agreement containing, in substance, the provisions required by sections 26(a)(2) and (3) of the Act. Applicants state that, except for Fund shares, which will be maintained in an open-account system, Account A's only assets will consist of amounts of cash from time to time. Such cash will be kept on deposit in the name of Account A with a bank meeting the requirements of section 26(a)(1).

Section 26(a)(2)(D) of the Act requires, in part, that under the agreement with the trustee or custodian, such entity must have possession of all the securities and other property in which funds of a unit investment trust are invested. Applicants state that this has been interpreted to mean that the securities owned by the trust must be represented by share certificates physically in the custody of the custodian. Section 26(a)(2)(D) of the Act also requires that the agreement with the trustee or custodian provide that the securities and other property in which the funds of a unit investment trust are invested must be segregated and held I trust until distribution. Applicants assert that while the assets of Account A will be segregated, VALIC, as a life insurance company, may not properly place assets of the Separate Account in trust, because the insurance laws of the State of Texas require VALIC to retain ownership and control of the disposition of its property. Applicants state that VALIC will continue to hold in custody for safekeeping the assets of Acount A until Account A has been completely liquidated and the proceeds of the liquidation distributed to persons entitled thereto under the Contracts or until a successor trustee or custodian is appointed. The application states the VALIC will maintain a record of the names and addresses of all owners and annuitants and the amount of their interest in Account A, and that Applicants will comply with the notice requirements of section 26(a)(4).

Applicants request exemptions from sections 26(a)(2)(D) and 27(c)(2) of the Act in order that assets of the Separate Account, including uncertificated shares of American General Equity Accumulation Fund, Inc., may be held by VALIC under the terms and conditions set forth in the application.

Approvals Under Section 11

Section 11(a) of the Act makes it unlawful for any registered open-end investment company or any principal underwriter for such a company to make or cause to be made an offer to the holder of a security of such company or of any other open-end investment company to exchange his security for a security in the same or another such company on any basis other than the relative net asset values of the respective securities to be exchanged, unless the terms of the offer have first been submitted to and approved by the Commission. Section 11(c) provides that, irrespective of the basis of exchange, the provisions of subsection (a) shall be applicable to any offer of exchange of any security of a registered open-end company for a security of a registered unit investment trust and to any type of offer of exchange of the securities of registered unit investment trusts for the

securities of any other investment company.

Applicants state that they do not believe that sections 11(a) or 11(c) should be interpreted to require Commission approval of transfers between divisions of Account A pursuant to the Contracts. Nevertheless, to remove any uncertainty, Applicants request Commission approval under those sections, to the extent necessary to permit owners, annuitants and beneficiaries to effect transfers between Divisions One and Two and Division Three pursuant to the Contracts. Applicants submit that such transfers will be effected at net asset value and will not generate any increased revenues or fees to VALIC or its affiliates. Therefore, Applicants believe the transfers between Account A's divisions contemplated by the Contracts are consistent with the purposes of sections 11(a) and 11(c) of the Act and the terms thereof should be approved by the Commission.

Section 6(c)

Section 6(c) of the Act, in pertinent part, provides that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of the Act to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, no later than July 6, 1982, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his or her interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he or she may request that he or she be notified if the Commission shall order a hearing thereon. Any such communications should be addressed: Security, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon the Applicants at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0–5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following July 6, 1982, unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notice and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-16606 Filed 6-21-82; 8:45 am]

BILLING CODE 8010-01-M

VETERANS ADMINISTRATION

Availability of Report of 38 U.S.C. 219 Program Evaluation

Notice is hereby given that the program evaluation of the Veterans Administration's Automobile and Adaptive Equipment Program has been completed.

Single copies of the Automobile and Adaptive Equipment Report are available free. Reproduction of multiple copies can be arranged at the user's expense.

Direct inquiries, specifying the name of the program evaluation desired, to Mrs. Lynn H. Covington, Acting Director, Program Evaluation Service, Veterans Administration (074), 810 Vermont Avenue, N.W., Washington, D.C. 20420.

Dated: June 14, 1982.

Robert P. Nimmo,

Administrator.

[FR Doc. 82-16761 Filed 6-21-82; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 120
Tuesday, June 22, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94–409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10:30 a.m., June 24, 1982.

LOCATION: Engineering Laboratory, 10910 Darnestown Road, Rockville, MD.

STATUS: Open to the public.

MATTER TO BE CONSIDERED:

1. *Current Leakage Test*
The staff will brief the Commission and conduct a demonstration on electrical current leakage testing.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Deputy Secretary, Office of the Secretary, Suite 342, 5401 Westbard Avenue, Bethesda, MD 20207; Telephone (301) 492–6800.

[S–924–82 Filed 6–18–82; 2:50 pm]

BILLING CODE 6355–01–M

2

FEDERAL RESERVE SYSTEM: Board of Governors

TIME AND DATE: 10:00 a.m., Monday, June 28, 1982.

PLACE: Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Proposals with respect to contempraneous reserve requirements (Proposed earlier for public comment; Docket No. R–0371).

2. Proposals for the treatment of seller's points under Regulation Z (Truth in Lending).

* Proposed 1983 budget objectives for the Federal Reserve System.

* Anyone planning to attend specifically for Item 3 should call 452–3206 on June 25, 1982, to assure that it has not been postponed to a future meeting.

4. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 18, 1982.

James McAfee,

Associate Secretary of the Board.

[S–922–82 Filed 6–18–82; 2:43 pm]

BILLING CODE 6210–01–M

3

FEDERAL RESERVE SYSTEM: Board of Governors

TIME AND DATE: Approximately 12 noon, Monday, June 28, 1982, following a recess at the conclusion of the open meeting.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 18, 1982.

James McAfee,

Associate Secretary of the Board.

[S–923–82 Filed 6–18–82; 2:43 pm]

BILLING CODE 6210–01–M

4

FEDERAL RESERVE SYSTEM: Board of Governors

TIME AND DATE: 10:00 a.m., Friday, June 25, 1982.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Request by the General Accounting Office for Board comment on a draft report regarding bank examination for country risk and international lending.

2. Proposed consideration of policy with respect to net settlement services.

3. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

4. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 17, 1982.

James McAfee,

Associate Secretary of the Board.

[S–917–82 Filed 6–17–82; 4:05 pm]

BILLING CODE 6210–01–M

5

METRIC BOARD

Bimonthly Board Meeting

TIME AND DATE: 9 a.m. to 5 p.m., Thursday, July 8, 1982; 9 a.m. to 11 a.m., Friday, July 9, 1982.

PLACE: Arlington Hyatt Hotel, Revensworth Hall/East, 1325 Wilson Blvd., Arlington, Virginia 22209.

STATUS: The meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Approval of Agenda—Approval of agenda for this meeting.

Review/Approval of Minutes of the Board Meeting held on May 6–7, 1982 in Arlington, Virginia.

Committee Final Reports—Committee Chairmen will make a final report to the Board.

Perspectives on Roles in Future Metric Activity—The Board will receive presentations by the organizations expected to survive the Board and continue administration of elements of the Metric Conversion Act. Panelist representing the ICMP/MOC, States (NCSM Executive Committee), ANMC and the Department of Commerce will address the Board.

Final Standards Report and Recommendations—Staff will review the Board's standards reports and discuss the results of the work and findings. The Chairman of the Planning and Coordination Committee will introduce standards recommendations for approval by the Board.

Factors of Concern to Small Business—Presentation to the Board by the contractor of the three models developed to assist

small firms in assessing the practicality of metric conversion for them.
Small Business Productivity—Mr. Bruce Phillips of the Small Business Administration will brief the Board. This project is being conducted through an interagency agreement with the Small Business Administration and has the purpose of investigating the statistical relationships between productivity, profitability, size , industry and other economic factors and metrication.
Research Utilization—A brief presentation, for information, will be provided to summarize what action has been taken to distribute the findings and increase the awareness of the Board's Research program.
Final Finanacial Report—The Executive Director will brief the Board on FY 82 expenditures.
Feasibility of a September Board Meeting—The Board will determine whether a September Board meeting is required to dispose of any remaining business for FY 82.

CONTACT PERSON FOR FURTHER INFORMATION: Lu Verne V. Hall, Staff Assistant, 703/235–1696.

Louis F. Polk,

Chairman.

[S–920–82 Filed 6–18–82: 9:53 am]

BILLING CODE 8260–01–M

6

METRIC BOARD

Planning and Coordination Committee Meeting

TIME AND DATE: 1:00–1:30 p.m., Wednesday, July 7, 1982.

PLACE: United States Metric Board, 1600 Wilson Blvd., Suite 400, Arlington, Virginia 22209.

STATUS: The meeting is open to the public.

MATTERS TO BE CONSIDERED:

Approval of Agenda
Review and Approval of Committee Report and Recommendations on Standards
Review and Approval of one-page Final Report to the Board by the Committee and Recommendations for disolution of the Committee
Other business

CONTACT PERSON FOR FURTHER INFORMATION: Alan Whelihan, 703/235–2919.

Louis F. Polk,

Chairman.

[S–919–82 Filed 6–18–82: 9:53 am]

BILLING CODE 8260–01–M

7

METRIC BOARD

Research Committee Meeting

TIME AND DATE: 11 a.m. to 1 p.m., Wednesday, July 7, 1982.

PLACE: United States Metric Board, 1600 Wilson Blvd., Suite 400, Arlington, Virginia 22209.

STATUS: The meeting is open to the public.

MATTERS TO BE CONSIDERED: Three Briefings on Research Activities: (1) General Status Briefing of Research Projects; (2) Discussion on Methodology and progress of the Small Business Metrication and Productivity Project; (3) Presentation of Three Models on the Small Business Factors of Concern Study.

CONTACT PERSON FOR FURTHER INFORMATION: G. Edward McEvoy, 703–235–1697.

Louis F. Polk,

Chairman.

[S–921–82 Filed 6–18–82: 9:53 am]

BILLING CODE 8260–01–M

8

UNITED STATES RAILWAY ASSOCIATION

Board of Directors Annual Meeting

DATE AND TIME: June 24, 1982; 10 a.m.

PLACE: Board Room, Room 2–500, fifth floor, 955 L'Enfant Plaza North, S.W., Washington, D.C.

STATUS: The first portion of the meeting will be closed to the public; the second portion will be open.

MATTERS TO BE CONSIDERED: Portion Closed to the Public (10 a.m.):

1. Internal Personnel Matters.
2. Litigation Report.
3. Review of Conrail Confidential and Proprietary Financial Information.

Portion Open to the Public (10:30 a.m.):

4. Approval of Minutes of May 27 Board Meeting.
5. Election of Officers.
6. Section 211(h) Loan.
7. Section 211(h) Loan Forgiveness For Conrail.
8. Conrail Request for Waiver of Financing Agreement.
9. Conrail Monitoring Indicators.

CONTACT PERSON FOR MORE INFORMATION: Alex Bilanow, (202) 488–8777, ext. 505.

[S–918–82 Filed 6–18–82: 8:51 am]

BILLING CODE 8240–01–M

federal register

Tuesday
June 22, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Menstrual Tampons; User Labeling

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 80N-0425]

Menstrual Tampons; User Labeling

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require manufacturers of menstrual tampons to include information on toxic shock syndrome (TSS) in the labeling of the device. TSS is a rare, but serious and sometimes fatal, disease associated with tampon use. FDA is requiring that menstrual tampon packages contain a brief statement alerting consumers to the dangers of TSS and advising them to read and save information about TSS included in a package insert. If the TSS information itself is placed on the package, no alert statement is required. The language of the alert statement is specified, but tampon manufacturers may develop the information about TSS within guidelines specified in the final rule.

EFFECTIVE DATE: The regulation will take effect for packages of tampons initially introduced or initially delivered for introduction into commerce December 20, 1982.

FOR FURTHER INFORMATION CONTACT: Maria Donawa, Bureau of Medical Device (HFK-300), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7175.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 21, 1980 (45 FR 69840), FDA proposed a regulation that would have required a warning statement concerning TSS on the label of menstrual tampon packages. Interested persons were given until November 20, 1980 to comment on the proposed rule. In response to two requests and because new information had become available, in a notice published in the Federal Register of April 28, 1981 (46 FR 23766), FDA reopened the comment period until June 29, 1981. More than 300 comments were received from consumers, manufacturers, Government health departments, consumer organizations, and industry organizations. Almost all comments supported some form of labeling concerning TSS. The following summarizes the substantive comments received and FDA's responses to them.

General

1. A comment urged FDA to implement a nationally publicized campaign warning about the dangers associated with tampons and TSS.

As discussed at length in the April 28, 1981 notice, since publication of the proposed rule, information concerning TSS has been widely disseminated through the efforts of FDA, the Centers for Disease Control (CDC), State health agencies, tampon manufacturers, health professionals, and the news media. FDA intends to continue to provide information through press releases and professional, consumer, and industry education programs. Moreover, the labeling required by this rule will ensure continued dissemination of information. Thus, FDA believes that the goals of a national campaign are being met.

2. Comments argued that a warning statement on the package label of tampons is not necessary because manufacturers have already initiated education programs about TSS and tampons and because surveys show a minimum of 95 percent of women between the ages of 15 and 50 are familiar with the association of TSS and tampons.

FDA recognizes that publicity and actions taken by tampon manufacturers have done much to inform women of the association between TSS and tampon use. Nevertheless, the seriousness of TSS coupled with the potential for many new users require that information concerning TSS symptoms and what to do if those symptoms occur need to be continually provided to women who use tampons. Moreover, the effects of earlier publicity reasonably can be expected to diminish. For these reasons, FDA believes that information about TSS needs to be available on an ongoing basis. The final rule requires, therefore, that TSS information be included in a package insert with a brief statement on the outer package label calling attention to the insert or that all the information be on the package.

3. Comments suggested that the warning label is no longer necessary because the incidence of TSS is decreasing following the removal of Rely® brand tampons from the market. Comments noted that the geographic distribution of TSS cases is not consistent with the nationwide marketing of most tampon brands. Opposing comments said that the decline was illusory due to underreporting as a result of waning media interest.

Although there was a decrease in TSS cases reported to CDC following the peak of about 120 cases per month in August and September 1980, CDC advises that TSS cases have plateaued and continue to be reported at a national rate of about 50 per month. CDC further advises that "Assuming that the surveillance system detects approximately 15 percent of the cases which actually occur, it can be estimated that the true rate of severe cases of TSS is 300 to 400 per month; if milder cases of TSS are as common as severe cases, the actual rate of disease is in the vicinity of 600 to 800 cases per month" (CDC comments, June 29, 1981). Concurrently, the number of cases reported to the Minnesota Department of Health through May 1981 has shown no significant change in incidence before and after removal of Rely® brand tampons from the market (Ref. 1). FDA disagrees, therefore, that there is a basis for concluding that the incidence of TSS is now decreasing or that the incidence of TSS is related solely to use of Rely® brand tampons.

A nonuniform geographic distribution of TSS cases would be consistent with the distribution of many other diseases reported to CDC. Any such lack of uniformity can be explained in the case of TSS by noting the extensive surveillance done in the States with many cases, and the assumption made that all States would show the same number of cases relative to their population if their surveillance efforts were equal. More importantly, as noted above, no significant variation was seen in incidence before and after the removal of Rely® brand tampons from the market, and TSS cases continue to be reported at a national rate of about 50 per month. For these reasons, FDA disagrees that any nonuniform geographical distribution of TSS cases alleviates the need for tampon labeling.

FDA is concerned that many people seem to believe that the incidence of TSS is decreasing. An often quoted estimate of TSS incidence is 6.2 per 100,000 menstruating girls and women per year and originates from data from the Wisconsin Division of Health (see April 28, 1981 notice). As of January 1981, the reported incidence in Utah was 17 per 100,000 menstruating girls and women per year. Minnesota in its comments on the April 28, 1981 notice estimates an overall incidence of 6.6 per 100,000 menstruating girls and women per year. Based on these studies and the CDC data, which are the most comprehensive currently available, the agency believes that TSS continues to occur and that a reasonable estimate of current incidence is between 6 and 17 per 100,000 menstruating girls and women per year. To assure that users

are informed about current incidence, FDA is requiring that manufacturers provide information on estimated incidence.

4. A comment argued that there is no substantial evidence of record establishing a statistically significant association between TSS and brands of tampons other than Rely® brand or a material risk of contracting TSS from each brand/absorbency of tampons, citing *Council for Responsible Nutrition* v. *Goyan*, (1979–1980 Transfer Binder) Food, Drug, Cosmetic L. Rep. (CCH) ¶ 38,057 (D.D.C. August 1, 1980).

FDA rejects the comment. The legal standard applicable to this rulemaking is that the agency's action be "consistent with its statutory mandate, rational, and not arbitrary." *Pacific Legal Foundation* v. *Department of Transportation*, 593 F. 2d 1338, 1343 n. 35 (D.C. Cir. 1979). As the court explained in *Council for Responsible Nutrition* v. *Goyan*, "In the ultimate, the test is one of reasonableness."

The evidence on which FDA relies in this rulemaking is discussed or referred to throughout this preamble, particularly in paragraphs 5, 8, 9, 21, 27, and 31. In reaching its determination to issue the final rule, as in deciding on the appropriate regulatory response to many public health problems, FDA had to grapple with uncertainties, as well as with continually developing new information. Indeed, it was largely because of questions raised in the comments on the October 2, 1980 proposal and because new information became available within a reasonable time after publication of that proposal, that FDA reopened the comment period to provide an opportunity to comment on the new studies, information, and analyses. But few, if any, sets of scientific data ever provide the basis for drawing conclusions with certainty, and further delay would ill serve the interests of the public health.

The Federal Food, Drug, and Cosmetic Act (the act) and similar remedial statutes "demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable * * *. Awaiting certainty will often allow for only reactive, and not preventive, regulation." *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 25 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976). Thus, the courts appropriately have concluded that:

> Regulators * * * must be accorded * * * a flexibility that recognizes the special judicial interest in favor of the protection of the health and welfare of people, even in areas where certainty does not exist. *Id.* at 24.

In FDA's judgment, the evidence before it reasonably supports the conclusion that there is a statistically significant association between TSS and brands of tampons other than Rely® brand and that the final rule should apply to all brands and absorbencies of tampons.

5. A comment said that not all the provisions of the proposed warning are authorized by sections 201(n) and 502(a) of the act (21 U.S.C. 321(n) and 352(a)). This comment points out that section 201(n) of the act provides that, in determining whether a product is misbranded, FDA shall take into account whether the labeling "fails to reveal facts * * * material with respect to consequences which may result from the use of the article to which the labeling or advertising relates * * *." The comment says further that the statement that a woman "can almost entirely avoid the risk of getting (TSS) by not using tampons" is not a material fact with respect to the consequences of the use of tampons.

FDA disagrees with the comment. Based on the evidence of the increased risk of TSS associated with the use of tampons, particularly by young women and girls, the severity and rapid onset of the disease, and the significant risk of death for users who contract TSS, FDA has concluded that failure to inform consumers about the disease constitutes omission of material facts about the products. Under the final rule, any such omission from the labeling of tampons renders the labeling false or misleading within the meaning of sections 502(a) and 201(n) of the act, and the products, therefore, misbranded.

FDA has reviewed the specific wording in the proposal to the effect that a woman can almost entirely avoid the risk of getting TSS by not using tampons. Because the number of TSS cases that are not menstrually associated has appeared to increase it may no longer be correct to say that TSS can almost entirely be avoided by not using tampons. FDA has modified the wording to reflect that it is tampon-associated TSS that can be avoided by not using tampons and has provided this as guidance on the content of labeling required by the final rule.

6. Several comments argued that it was inappropriate to combine the data from two studies as FDA did in its notice reopening the comment period.

FDA recognizes that all statistical analyses involve assumptions upon which the validity of resulting statistical inferences depend. Seldom, if ever, can the data analyst be sure all assumptions are met, and, indeed, often the data analyst knows they are not met. Yet conclusions must be drawn and decisions made utilizing all available information. It is a common and accepted practice, if no better method is available, to use a method of analysis (statistical model) in situations known to diverge by a tolerable amount from required assumptions. The data analyst bears in mind the possible degree of divergence from assumptions along with the effect any such divergency may have on the accuracy of the analyst's conclusions (i.e., the robustness of the statistical test), then proceeds to draw the conclusions with all due caution.

In this case FDA's reasoning was as follows: Both the second CDC study (CDC 2) and the study conducted by the Utah State Department of Health (Utah Study) were made to draw inferences about the same hypothesis, i.e., an association between tampon use and TSS. The fact that the two sets of data were gathered in different locations using somewhat different survey techniques was not considered as important as the fact that both sets of data contained information about the same hypothesis and that both sets of data, when analyzed separately, were not found to be different (i.e., heterogeneous). For these reasons, the data were combined and reanalyzed in the usual manner.

7. A manufacturer commented that analysis of the combined CDC 2 and Utah Study data was done on unmatched cases and controls.

FDA was aware that its analysis was done on unmatched cases and controls. As discussed in the April 28, 1981 notice, the agency compared these groups in terms of such variables as income, race, education, and marital status, and found no important differences. Because the cases and controls were unmatched, however, FDA specified the statistical tests used in its analysis, i.e., Fisher's exact and chi-square.

8. A comment said that FDA was attempting to apply the same rule to dissimilar products contrary to the holdings in *United States* v. *Nova Scotia Food Products Corp.*, 568 F. 2d 240 (2d Cir. 1977) and *Council for Responsible Nutrition* v. *Goyan*. Another comment argued that there is no evidence in the record of an association between the use of a recently introduced cotton tampon with no super-absorbent materials and the occurrence of TSS. Another manufacturer said that the incidence of TSS among users of its product is less than would be expected when compared to the percentage of controls in the studies using its product and its general market share.

FDA disagrees with these comments. Applying principles developed in Consumer Product Safety Commission (CPSC) cases, FDA may not impose the same warning requirements on a product that exhibits "significantly dissimilar functional or risk characteristics when compared with the other products" to which those requirements apply, unless FDA reasonably determines either (1) that the product presents no significantly dissimilar functional or risk characteristics that are pertinent to the objectives of the warning; or (2) that despite significant differences, application of the warning to the product remains reasonably necessary to prevent or reduce an unreasonable risk of injury associated with the product. *ASG Industries, Inc.* v. *CPSC*, 593 F. 2d 1323, 1330 (D.C. Cir.), *cert. denied*, 444 U.S. 864 (1979); *Southland Mower Company* v. *CPSC*, 619 F. 2d 499, 506–07 (5th Cir. 1980). Once FDA justifies the need for a warning affecting a general category of products, however, the burden shifts to a manufacturer to show that an individual product should be excluded from the general warning requirement. FDA is not, in the first instance, required to make an individual determination that a warning should apply to each particular product within a general category of products. *Cosmetic Toiletry & Fragrance Association* v. *Schmidt*, 409 F. Supp. 57, 61 (D.D.C. 1976), *aff'd without opinion*, Civil No. 7515 (D.C. Cir. August 19, 1977); *Bunny Bear, Inc.* v. *Peterson*, 473 F. 2d 1002 (1st Cir. 1973).

The April 28, 1981 notice discussed FDA's conclusion that there is a statistically significant association between the use of all brands of tampons and the occurrence of TSS. This association is confirmed by the tri-State study even if the data concerning Rely® brand are excluded (Ref. 1). FDA also concluded that the data do not show any statistically significant difference in relative risk from tampons other than Rely® brand, and that the relative risk is material for all brands and styles of tampons, including Rely® brand.

There has been speculation that TSS is in some way related to tampon fibers, materials, construction, or functional characteristics. None of the data available to FDA, however, shows that there is an association between the occurrence of TSS and (1) a particular tampon fiber, ingredient, or combination of ingredients (see paragraph 27) or (2) any other product characteristic, including tampon materials, construction, design, or the manner in which the device functions (see paragraph 31). FDA concludes, therefore, that there is no justification for excluding from the requirements of the final rule any brand of tampon based on its fibers, ingredients, materials, construction, design, or functional characteristics.

FDA recognizes that the data from the tri-State study do not prove a statistically significant association between the use of certain styles of certain brands of tampons and the occurrence of TSS. The tri-State study, therefore, can neither confirm nor disprove that TSS is associated with each style of each branch of tampons. FDA also recognizes that the tri-State study indicates that there are substantial differences in relative risk from certain styles of certain brands of tampons. The tri-State study does not, however, contain enough TSS cases for each style of tampons to show statistically significant differences in risk. For these reasons, FDA continues to conclude that there is an association between TSS and all tampons, and that no style of tampon presents a significantly different risk characteristic when compared to other tampons generically. The association between TSS and all tampons remains; the tri-State data do not justify a conclusion that a particular style or any brand of tampons should be excluded from the requirements of the final rule but the tri-State and the other data discussed or referred to throughout this preamble are adequate to include all tampons.

The relationship between TSS and tampon "absorbency," as defined in the tri-State study, though not unimportant, is uncertain. Indeed, the tri-State data concerning this relationship are insufficient to predict accurately the risk for each tampon brand or the relative risk among different brands of tampons. For this reason and the reasons discussed in this paragraph and in paragraph 21, FDA has determined that absorbency is not a basis upon which to exclude any style or brand of tampon from the requirements of the final rule. Nonetheless, because the risk of TSS appears to decrease as tampon absorbency decreases, the final rule requires that product labeling advise women to use tampons with the minimum absorbency needed to control menstural flow (see paragraph 21).

Differences in general market share and the percentage of controls in the studies using a particular product are small in comparison to the strong statistical association of all brands of tampons and the occurrence of TSS. Even if tampons with a particular fiber, ingredient, material, design, construction, or functional characteristic were shown to exhibit significantly dissimilar risk characteristics and consumers could identify those tampons from product labeling, application of the final rule to them would still be necessary to protect the public health and minimize the serious effects of TSS because all tampons are associated with TSS.

Apart from the argument that because the incidence of TSS among users of its product is less than would be expected when compared to the percentage of controls in the studies using its product and its general market share, the manufacturer that argued that FDA is improperly attempting to apply the same rule to dissimilar products has not brought to FDA's attention any evidence other than the tri-State study to support the claim that certain styles or brands of tampons should not be covered by the final rule. Neither have other manufacturers shown why their products should not be subject to the requirements of the final rule. Accordingly, FDA has concluded that the final rule will apply to all styles and brands of tampons.

9. A comment argued that FDA may not rely in this rulemaking on the analysis of statistical significance presented in the Commissioner's decision on cyclamates, because the decision whether to require a warning label on tampons is not analogous to FDA's decision denying approval of cyclamates as a food additive. According to the comment, the critical difference is that in cyclamates the sponsor bore the burden of proof of safety, whereas here FDA bears the burden of proving that there is a material risk of TSS from each brand/absorbency of tampons.

FDA disagrees with the comment. FDA relied in part on the analysis of statistical significance presented in the Commissioner's decisions on cyclamates and Benylin, because, as the agency pointed out in the April 28, 1981 notice, the standard of $P<0.05$ is grounded in custom not science or law. FDA then pointed out that the CDC 2 study showed a borderline ($P=0.053$) statistically significant association between TSS and tampons other than Rely® brand and that this showed that there is a 94.7 percent probability that the result is not due to chance. FDA believes that the difference between a 94.7 percent probability and a 95 percent probability is not substantial, and that, considering the particularly high incidence of TSS in young women and girls, the severity and rapid onset of

TSS, and the risk of death for users who contract TSS, a finding of material risk can be based on the former probability.

10. A manufacturer argued that FDA has established tolerance levels for aflatoxin B in peanuts and polychlorinated biphenyls (PCB's) in fish which result in a lifetime risk of cancer greater than the risk of contracting TSS associated with its product. The comment also noted that FDA has not deemed it necessary to establish warning labels for foods containing chlorinated water, even though the lifetime cancer risk is alleged by the comment to be between 1–10 per 100,000. Because the manufacturer believes the risk of TSS associated with the use of its brand of tampons is extremely small and significantly below the level of risk FDA has accepted with other products, the manufacturer claims that it would be inconsistent for FDA to require a warning about TSS on its product.

FDA disagrees with this reasoning. Each regulatory problem must be examined in its own circumstances. The studies supporting this final rule are based on actual instances of TSS occurring in humans and show that there is a statistically significant association between all brands of tampons and the occurrence of TSS, that is, a quantifiable human risk under actual use conditions. By contrast, any levels of risk attributed to aflatoxin- and PCB-"contaminated" food, expressed as upper bounds, are based primarily on extrapolations of animal data to humans and of high dose data to lower dose use. There are no data reflecting actual exposure to these substances over defined periods of time by particular individuals who develop cancer. FDA does not regulate the chlorinating of water, which is under the jurisdiction of the Environmental Protection Agency.

FDA believes, as discussed in paragraph 3, that a reasonable estimate of the risk of TSS is between 6 and 17 per 100,000 menstruating women and girls per year, and may be even greater due to underreporting. Also, for certain age groups, the risk is considerably greater than that estimated for the affected population generally (see paragraph 20). Over many years of tampon use, the resulting lifetime risk, derived from actual human experience, would be much greater than any risks assessed for animal carcinogens and described in the comment. Furthermore, every tampon poses some risk of TSS. There is no evidence that all foods pose a risk of cancer from aflatoxin and PCB's, or that food inherently poses a risk of cancer. Tampons do inherently pose a risk of TSS.

For these reasons, FDA believes that different treatment of any risk of cancer from "contaminated" foods and the risk of TSS from tampons is justified, and concludes that the circumstances of this regulatory problem warrant warning consumers about TSS on tampon packages.

Package Insert

11. Several manufacturers suggested that a package insert is more appropriate than a warning on the outer package label because it would allow greater flexibility for new knowledge, it would provide more space, and it could be processed to reach the consumer more quickly. Many comments, especially from consumer groups and individual consumers, said that FDA should require manufacturers to include in each package of tampons a package insert concerning TSS in addition to the outside warning. These comments suggested that the insert should contain information about the symptoms and development of TSS, statistics on its incidence, and actions one can take to lower the risk of TSS. Other comments said that the package insert should be short and concise to ensure that it would be read. Yet other comments said that there should be a statement on the outside of the package to draw attention to the package insert. Some comments said that FDA should not require package inserts because they would be costly and, in most cases, consumers would not read them, and that the outside labeling is sufficient to inform the consumer of the problem. A comment said that the placement of information on the outside of a package to draw attention to the insert would encourage consumers to break into packages in the store, causing economic loss to the retailer.

FDA has concluded that useful, substantive information on TSS must be provided on the package or in a package insert. FDA also believes that a short statement is needed on the outside of the package directing the attention of consumers to the package insert if a manufacturer elects to provide information in that way. FDA notes that most tampon packages already contain inserts. Manufacturers may either adapt current inserts to include the required TSS information or use separate inserts. If a package insert of either type is included, a short statement on the outside of the package is necessary to improve the likelihood that users will read and save the package insert. FDA believes it unlikely that consumers will break into packages in the store to read the package insert.

Therefore, FDA is requiring in the final rule that tampon packages include a package insert containing specified information about TSS in terms understandable by the layperson, and that the outside of the package be labeled with a short statement alerting consumers to the dangers of TSS and to the existence of the insert, or that all the information be included on the package.

Contents of Warning

12. A comment suggested that manufacturers should be permitted to vary the wording of the warning, subject to FDA's approval.

FDA has modified the proposed requirement that would have specified the wording of a warning statement on the package. In preparing the final rule, FDA accepted part of the intent of this comment. The final regulation will allow manufacturers to develop their own wording for TSS information provided that certain topics specified in § 801.430(d) are addressed adequately in terms understandable by the layperson and no false or misleading information is presented. If a package insert is used to present the information, however, § 801.430(c) in the final rule requires the following alert statement to be placed on the product package, "ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information." Thus, provided the topics specified by § 801.430(d) are addressed, the wording of the TSS information may be varied. The agency concludes, however, that the alert statement needs to be uniform to assure that consumers are equivalently informed of the availability of TSS information.

13. Comments suggested that FDA require that the word "WARNING" on the outside label be in letters larger than the remainder of the warning statement and be printed in bright red.

FDA notes that the final regulation does not require that the word "WARNING" be used in the alert statement because the message on the outside of the box is intended to direct consumers to other TSS information if that information is included as a package insert. Paragraphs (c) and (d) of § 801.430 of the final rule require all information placed on the package label to be prominent and legible. FDA believes that it is not necessary to describe further the color or the manner in which outer package statements need to be presented.

14. A comment suggested that the warning should be shorter to make it more likely to be read. To accomplish this, the comment suggested that the last sentence warning about the symptoms of TSS be omitted.

FDA agrees in part with the comment. Under the final rule, if the manufacturer elects to use a package insert, the short statement described in paragraph 13 is required to be placed on the package label, and information about TSS warning signs and what to do if they appear is required to be included in the insert. This information should always be provided, either in an insert or on the package, to alert women about the circumstances in which they should seek medical attention.

15. Comments suggested that FDA not require the inclusion in the warning of the statement, "You can almost entirely avoid the risk of getting this disease by not using tampons. You can reduce the risk by using tampons on and off during your period." The comments said that these statements are not justified by the scientific evidence. A comment said that the first part of the statement is unwarranted because it has not been established that tampons cause TSS. Another comment stated that this requirement is unprecedented because in no other case does FDA require a statement suggesting that the consumer may not want to use the product.

FDA does not maintain that tampons are the cause of TSS. As discussed elsewhere in this preamble, FDA concludes that current scientific evidence demonstrates a statistically significant association between the use of tampons and the occurrence of TSS. FDA recognizes that not all risk of TSS can be eliminated by not using tampons because TSS occurs among nonusers of tampons; however, the risk of contracting TSS that is directly associated with the use of tampons can be eliminated by not using the product. Furthermore, CDC advises that its studies show that continuous use throughout the menstrual period increases the risk (see Ref. 2, April 28, 1981 notice). The proposed warning may be unprecedented in that it advises the consumer that one way to avoid the disease associated with the product is not to use the product. Nevertheless, the information is sound in terms of protection of the public health. The purpose of the statement is to advise women of the dangers associated with the use of tampons so that they can make an informed decision on whether and how to use the product. The significant difference between this statement and other warnings typically found on FDA-regulated products is that the statement itself sets forth the conclusion that is inherent in other such warnings, viz., do not use the product if you wish to avoid the risk associated with it. FDA, therefore, disagrees with the comments and is requiring in the final rule that information provided with tampon packages include a statement concerning avoiding the risk of tampon-associated TSS by not using tampons and possibly reducing that risk by alternating tampon use with sanitary napkin use.

16. Several comments said that the statement, "You can reduce the risk by using tampons on and off during your period" is unclear. A comment suggested that the warning should be revised to include the statement, "You can reduce the risk associated with tampon use by alternating tampons with sanitary napkins or mini-pads; when tampons are used, they should be changed at least every 6 to 8 hours."

FDA agrees with those comments that suggested that the proposed warning is unclear. As discussed in paragraph 15, the agency has revised the final regulation to require a statement concerning possibly reducing the risk of TSS by alternating the use of tampons with sanitary napkins. Because mini-pads are a type of sanitary napkin, the agency believes that it would be redundant to require that reference to them be included in any statement provided with the package.

FDA is also concerned that few data support the benefit of any particular pattern of discontinuous tampon use. In addition, no evidence was submitted to demonstrate that the risk of TSS is decreased by changing tampons at specified intervals. Nor is FDA aware of such evidence. Therefore, FDA rejects the portion of the comment suggesting that the required information recommend that tampons be changed every 6 to 8 hours.

17. Comments suggested that the warning should address the need for personal hygiene in the use of tampons because lack of hygiene may contribute to TSS.

According to some theories, personal hygiene and other factors may affect the incidence of TSS. Although it has been reported that contraceptive use may protect against the development of TSS, to date, there has been no evidence demonstrating an association between poor personal hygiene and TSS. In the absence of data showing such an association, FDA believes that it would be inappropriate to require such information in the labeling.

18. A comment suggested that the first sentence of the warning statement should be revised to add the word "sometimes" before "fatal" to put a proper perspective on the incidence of fatalities from the disease.

FDA agrees with the intent of the comment. Where specific wording is required by the final regulation, the word "may" is used to convey the thought that death sometimes can result from TSS while maintaining the brevity of the alert.

19. A comment suggested that the words "FDA advises" should be added before the warning to give more weight to the warning.

The suggestion to add "FDA advises" is rejected. The agency believes that it would be misleading to limit the alert statement in this manner because the statement is based on advice from other sources, including CDC and other public health agencies, as well as considerable data developed since the disease first was reported.

20. Several comments suggested that the warning label should state that there is an increased risk of TSS for "younger women" or "women under the age of 20."

FDA has reviewed that portion of all cases of TSS reported to CDC where tampon use was known and combined this information with the use of tampons by different age groups. As seen in the chart below, many cases of TSS in known tampon users reported to CDC have occurred in women 30 years of age or younger and about half of these cases have occurred in women 21 years of age or younger. FDA then adjusted the number of cases in known tampon users by including the number of tampon users within age groups, as reported to the agency by the The Procter & Gamble Company, and calculated the relative number of cases per tampon user to approximate relative risks within different age groups. These adjusted data in the last column of the chart further confirm the hypothesis that younger women and teenage girls are at greater risk.

AGE DISTRIBUTION OF TSS CASES [1] IN KNOWN TAMPON USERS, INCLUDING ADJUSTMENT FOR TAMPON USE AT DIFFERENT AGES

Age at onset of TSS	Number of TSS cases in known tampon users	Number of tampon users (thousands)	Relative risk of TSS [2]
10-12	9	249	36
13-15	74	2,507	30
16-18	139	4,403	32
19-21	84	4,907	17
22-24	51	5,135	10
25-27	46	4,804	10
28-30	58	4,294	14
31-33	29	4,179	7
34-36	24	3,034	8

AGE DISTRIBUTION OF TSS CASES [1] IN KNOWN TAMPON USERS, INCLUDING ADJUSTMENT FOR TAMPON USE AT DIFFERENT AGES—Continued

Age at onset of TSS	Number of TSS cases in known tampon users	Number of tampon users (thousands)	Relative risk of TSS [2]
37-39	8	2,801	3
40-42	4	2,251	2
43-45	2	1,969	1
46-48	1	1,718	1

[1] Includes definite TSS cases and probable TSS cases that resulted in death as reported to CDC before June 19, 1981 (based on computer tape information provided to FDA by CDC). These 529 cases were confirmed as having occurred in women during a menstrual period while using tampons. Of the other 538 cases reported to CDC as of June 19, 1981, 6 were confirmed as having occurred in women who were not using tampons; because of insufficient data, 532 could not be confirmed as having occurred in women who were or were not using tampons.

In the April 28, 1981 notice, FDA stated that, according to CDC, onset in 905 of the 941 cases of TSS confirmed to CDC as of January 1981 occurred in women during a menstrual period while using tampons (46 FR 23768). This statement was incorrect. The 905 figure applies to women who had onset during a menstrual period, not to women who had onset during a menstrual period while using tampons. It is not known how many of the 905 women had onset while using tampons.

The absence of information concerning tampon use in the January and June 1981 CDC data is a problem unique to those data. In the CDC, tri-State, and other case control studies discussed or referred to throughout this preamble, data concerning tampon use, time of onset of TSS, and other relevant factors were confirmed.

[2] The value for relative risk at age 46–48 was arbitrarily set at 1 and the other values normalized to it to eliminate the need to present data in fractions of whole numbers.

Although the chart above shows a greater incidence of TSS in young women, FDA notes that cases have occurred in menstruating women of all ages and that it would be erroneous to assume that menstruating women over a certain age have an insignificant risk of getting TSS. Based on these data FDA is requiring a statement in the labeling concerning the higher reported incidence of TSS in younger women and teenage girls.

21. Comments suggested that the warning label should include a statement that there is an increased risk of TSS connected with the use of superabsorbent tampons.

The Tri-State study concludes that there is a statistically significant, i.e., detectable, association between TSS and tampon absorbency. The association with absorbency, however, does not allow a prediction of the risk of TSS for each tampon brand or even the relative risks of TSS among different tampon brands. Furthermore, there is no mandatory or voluntary standard, industry agreement, or other common understanding of the meaning of "super," "regular," or any other word used by manufacturers to characterize absorbency. Thus, even, if tampons with a particular level of absorbency were shown to exhibit significantly different risk characteristics from tampons generally, consumers could not identify those lower-risk tampons from product labeling. Because one study has detected a relationship between TSS and tampon absorbency, however, FDA believes that the required information should advise women that they should use tampons with the minimum absorbency needed to control menstrual flow. From a public health standpoint, this approach is consistent with the existing, but limited scientific data regarding the relationship of absorbency to the risk of the disease.

22. A comment said that the proposed warning is misleading because it is exaggerated and fails to provide a balanced and informative picture of the risk of TSS. The comment said that the proposed warning provides no information about the nature of the risk if a woman uses tampons and implies that the risk to be avoided is substantial.

FDA believes that the alert statement and consumer information required by the final rule will present an accurate picture of what is known about the risks of TSS and will not be misleading or exaggerated. The required information is based on several studies and FDA believes that it is the information that is necessary to allow women to make an informed decision as to whether and how to use tampons.

23. A comment asserted that unless the proposed warning was changed to eliminate "FDA's proposed permanent proscription on tampon use," the warning would be inconsistent with CDC's advice and would be unjustified.

FDA believes that CDC's advice and the warning proposed in the October 21, 1980 proposal are consistent. CDC advised that the risk of TSS can be reduced by using tampons for only part of the menstural period. In the final rule, FDA requires that information provided on or in the package include the same advice. The information required by the final rule, however, goes beyond the concept of reducing the risk of TSS and provides information on how women can eliminate the risk of tampon-associated TSS. Thus, CDC's advice is a subset of the information required by FDA and is consistent with it.

FDA is not attempting to proscribe the use of tampons. FDA emphasizes that the purpose of the final rule is to provide adequate information to women so that they can make informed decisions about whether and how to use tampons.

24. Several comments suggested that the required information on the TSS symptoms was inadequate because many women ordinarily have fever, vomiting, and diarrhea during their menstrual periods.

FDA developed the list of symptons based on CDC's case definition (see October 21, 1980 proposal, Ref. 3). The symptoms include not just a fever, but a sudden fever of 102° or more, together with vomiting or diarrhea. FDA believes that these symptoms are sufficiently uncommon to justify consulting a physician, and is, therefore, requiring that information about these symptoms be provided with the package.

Placement of Warning

25. A comment suggested that manufacturers be permitted to place the required warning on the back or side panel if the area of the principal display panel of a tampon package were less than 20 square inches and if the principal display panel contained the following: "WARNING: Tampons have been associated with toxic shock syndrome, a rare disease that can be fatal. For further information, see back (or side) panel." Another comment suggested that manufacturers be permitted to put the warning somewhere other than the principal display panel provided that it could easily be seen by the consumer. This comment said that the warning statement is disproportionate in size to the principal display panel of smaller packages of tampons and that inclusion of the warning would reduce the amount of other information that could be provided to the consumer, thus placing manufacturers of smaller packages of tampons at a competitive disadvantage. The comment also said that a requirement that the warning be placed on the principal display panel would provide little benefit to the consumer because, in many instances, the pincipal display panel would not face the consumer when the product is displayed on the store shelf.

Consistent with the intent of these comments, the alert statement required by the final regulation when a package insert is used for TSS information is considerably shorter than the warning that would have been required by the proposed regulation. FDA believes that this statement can be prominently and legibly placed on all sizes of tampon packages. FDA has concluded that there is no need to require that the alert statement appear in any specific location, thus providing flexibility to manufacturers. Likewise, if a manufacturer elects to place all the required TSS information on the package, it must be prominent and legible.

26. A comment argued that warning consumers of the possibility of death from the use of tampons would frighten consumers rather than inform them of the health risk.

As of October 1981, 1,407 cases of TSS had been reported to CDC of which 89 were known to have resulted in death. FDA believes that this is a significant

risk of death and that women should be informed of this possible outcome. The comment is rejected.

Listing of Fibers

27. Several comments, including one in the form of a citizen petition, suggested that TSS as well as other adverse effects, such as allergic reactions, are associated with tampons and urged that FDA require the labeling of tampons to include a complete listing of all fibers or ingredients used in the product.

Neither the petition nor the other comments presented data to establish an association between the occurrence of TSS and a particular tampon fiber, ingredient, or combination of ingredients. FDA is not aware of evidence to establish such an association. Therefore, FDA must deny the petition at this time and will not require the listing of fibers or ingredients in the product labeling. FDA also concludes that it does not have enough information about tampon-related allergic dermatitis to require ingredient labeling at this time based on this hazard. FDA is reviewing the problem of adverse reactions that might be associated with tampons to determine whether any FDA action in addition to that already underway in the voluntary standards community would be appropriate.

Prohibited Statements

28. Several comments said that FDA should prohibit any statement claiming or implying, without adequate scientific support, that one brand of tampon presents a reduced risk. Other comments suggested that FDA prohibit any statement in the labeling minimizing the danger of TSS. One comment suggested that FDA prohibit any statement claiming that tampons are more hygienic than other menstrual products.

Section 502(a) of the act provides that a device is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act describes some of the factors FDA is to take into account in determining whether labeling is misleading. FDA will not attempt in this document to enumerate any statements with regard to TSS or to tampons in general which are false or misleading. Instead, FDA will monitor the labeling of tampons in commercial distribution to determine their compliance with the act and the final rule.

Point of Sale Notices

29. Many comments suggested that FDA require that notices concerning TSS be posted at the point-of-sale of tampons. Those comments suggested that the notices should be in the form of posters, tearsheets, brochures, or all of these. Several other comments said that such notices would be costly, and would likely not be read by women.

The initial reason for urging point-of-sale notices was to ensure that consumers were alerted to the danger of TSS until manufacturers could provide information about TSS in the labeling of tampons. FDA believes that the tampon package and information provided with it, rather than a separate notice at the point-of-sale, is more effective in informing women about TSS and tampons.

Exemptions

30. Several comments said that FDA should not allow exemptions from the labeling requirements for any individual product without definitive proof that TSS is not associated with the product. Many of these comments expressed doubt that such proof exists at this time. Several comments stated that no exceptions should be allowed under any circumstances. A comment said that FDA's "citizen petition" process is not adequate for this purpose because the 180-day period for response is too long. Another comment said that the citizen petition process would be appropriate.

FDA is prepared to consider petitions for variance or exemption from its regulations, and will consider petitions for variance or exemption from this final rule. FDA believes that the citizen petition process provided in 21 CFR 10.30 of its administrative practices and procedures regulations is adequate and that it is not necessary to establish a separate process for considering exemptions from this final rule. FDA will attempt to respond sooner than the 180 days permitted by 21 CFR 10.30.

31. A comment argued that at least one tampon brand should be exempted based on differences in construction, design, or materials between it and Rely® brand. According to the comment, Rely® brand was designed to function as a "plug," whereas the other tampon brand was designed to function as a "cylinder which expands in all directions as it absorbs the menstrual flow." The commentor also argued that brands of tampons other than Rely® brand have significant design contrasts from the tampon it manufactures.

FDA rejects this comment because the case has not been made for exempting any brand of tampons based on product characteristics. None of the data available to FDA establishes a relationship between TSS and tampon construction, design, or materials. Even if Rely® brand differed somewhat in design from other tampons, and was intended to function as a "plug," neither the difference in design nor the difference in intended function has been shown to account for the risk of TSS from Rely® brand. Furthermore, although the tri-State study concluded that Rely® brand of tampons carried a risk somewhat larger than that which would have been expected given its greater absorbency, there is a statistically significant association between the use of all brands of tampons and the occurence of TSS, even if the data concerning Rely® brand are excluded.

32. Several comments questioned what the effect of the proposed regulation would be on tampons sold through vending machines. Some comments suggested that FDA should require that the warning be posted on the outside of tampon vending machines.

As proposed, the regulation would have required that any tampon sold through a vending machine be labeled with the warning. After further consideration, FDA does not believe that this proposed requirement is necessary. FDA also believes that it is not necessary to require that a warning statement be posted on the outside of vending machines. Women tend to purchase tampons from vending machines only infrequently. They will be made aware of the association between TSS and tampons from information provided with packages obtained from other retail sources. FDA has revised the regulation by providing in new § 801.430(e) that any tampon dispensed by a vending machine is exempt from the regulation.

Reclassification

33. Several comments recommended that menstrual tampons be reclassified from class II (performance standards) into class III (premarket approval). In addition, the Obstetrics-Gynecology and Radiologic Devices Panel, an FDA advisory committee, recommended that menstrual tampons be reclassified into class III.

Reclassification of tampons into class III would require a determination, among others, that this generic type of device presents a potential unreasonable risk of illness or injury (section 513(a)(1)(C)(ii)(II) of the act, 21 U.S.C. 360c(a)(1)(C)(ii)(II)). Although TSS is a serious and sometimes fatal disease, it is a rare disease. Also, TSS has not been shown to be caused by tampons, and FDA believes that it cannot be said that tampons, in and of themselves, present a potential

unreasonable risk to health. Furthermore, reclassification of tampons into class III is not likely to result in any increase in the safety of these products, and industry, government, and academic research is underway that is directed at the relationship between tampons and TSS. For these reasons, FDA has concluded that continued regulation of tampons as class II devices (21 CFR 884.5460 and 884.5470) is sufficient to provide reasonable assurance of their safety and effectiveness.

Automatic Expiration Date

34. A comment suggested that the regulation expire automatically at the end of 1 year or 18 months to allow for review of new scientific data and developments.

FDA believes that it would be inappropriate to establish an automatic expiration date for the regulation. FDA will, however, continue to monitor studies of the incidence of TSS in the population and, if new information is presented to warrant a change, will propose to modify or revoke the regulation. Final § 801.430(d) provides flexibility in providing information concerning what is known about tampons and TSS. Thus, FDA intends that new information would be included if and when it becomes available. The agency concludes that it would be inappropriate to provide for automatic withdrawal of the final rule at any specified future date.

Request for Hearing

35. A comment argued that pursuant to § 10.40(f)(2) of FDA's administrative practices and procedures regulations (21 CFR 10.40(f)(2)), FDA should hold a formal evidentiary public hearing on the proposed rule.

FDA disagrees with this comment and denies the hearing request. Section 10.40(f)(2) provides that, in its discretion, FDA may subject a proposed or final regulation to a hearing. Because FDA has concluded that the association of TSS with tampons is a significant public health problem that needs to be addressed as promptly as possible and because FDA already has provided several opportunities for all interested persons to present their views orally and in writing, FDA believes that it would not be in the public interest to subject the proposal to a formal evidentiary hearing under Part 12 (21 CFR Part 12).

36. A comment argued that FDA is required to hold a formal evidentiary public hearing before promulgating any final rule requiring a warning on the package label of tampons, citing *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council*, 435 U.S. 519 (1978).

FDA disagrees with this comment. Neither the act, FDA regulations, agency practice, nor the Administrative Procedure Act (APA) (5 U.S.C. 551–559, 701–706) requires any type of hearing for informal (notice and comment) rulemaking, which is governed by section 4(b) of the APA (5 U.S.C. 553). Contrary to the comment's argument, nothing in *Vermont Yankee* suggests that an agency is required to hold a trial-type hearing before promulgating a rule of general applicability in accordance with the procedures set out in section 4(b) of the APA. Indeed, under *Vermont Yankee*, congressionally enacted minimum requirements for informal rulemaking are also to be regarded as the maximum requirements. The case expressly cautions against judicial imposition of nonstatutory procedural requirements.

Effective Date

37. Several comments from manufacturers stated that 60 days would not be an adequate time for compliance with the regulation. A comment stated that 120 days would be needed; a manufacturer stated that it had a 4-month inventory and that another 90 days would be required to implement relabeling of the products manufactured after the final regulations became effective. Many comments from consumers and others stated that 60 days was an appropriate time. Comments suggested that accommodations could be made for putting stickers with the warning on the package. Comments also suggested that only manufacturers, not distributors or retailers, should be required to relabel products reintroduced into commerce after the effective date of the final rule.

Because all manufacturers are voluntarily providing some information concerning TSS on or in tampon packages, FDA believes that the final regulation should take effect for all tampon packages initially introduced or initially delivered for introduction into commerce 180 days after publication of the final rule. FDA believes that this effective date will provide manufacturers adequate time to meet the requirements of the final regulation with minimal disruption and without compromising the interests of the public health.

The following reference is on file in the Dockets Management Branch, Food and Drug Administration, and is available for public review between 9 a.m. and 4 p.m., Monday through Friday.

Reference

1. "Tri-State Toxic Shock Syndrome Study: Epidemiologic Findings", Presented to the Annual Society for Epidemiologic Research Meeting June 17, 1981 Snowbird, Utah, Osterholm, M. et al.

FDA examined the regulatory impact implications of the regulation in accordance with the criteria in section 1(b) of Executive Order 12291, and found that the regulation will not be a major rule as specified in the Order. The direct costs associated with labeling for toxic shock syndrome, as well as the indirect costs due to shifts in product preferences and sales, are both small. Further, for the most part, manufacturers have already labeled their tampon packages, and shifts in sales have already taken place. Neither the initial costs nor the annual costs associated with this regulation exceed the criteria for a major rule specified in the Order. The requirements for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final regulation because the proposed rules were issued prior to January 1, 1981, and are therefore, exempt. In any event, this regulation will not have a significant economic impact on a substantial number of small entities, for the reasons stated above. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen in that office between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Over-the-counter devices, Prescription devices, Requirements for specific devices.

PART 801—LABELING

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 502, 701(a), 52 Stat. 1041 as amended, 1050–1051 as amended, 1055 (21 U.S.C. 321(n), 352, 371(a)) and under 21 CFR 5.11 as amended (see 47 FR 16010; April 14, 1982), Part 801 is amended by adding new § 801.430, to read as follows:

§ 801.430 User labeling for menstrual tampons.

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Available data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to

minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c) and (d) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

(d) The consumer information required by this section shall appear prominently and legibly, in a package insert or on the package, in terms understandable by the layperson and shall include statements concerning:

(1)(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) Any menstrual tampon dispensed by a vending machine is exempt from the requirements of this section.

(f) Any menstrual tampon that is not labeled as required by this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, is misbranded pursuant to sections 502(a) and 201(n) of the act.

Effective date. This regulation becomes effective December 20, 1982 for menstrual tampon packages initially introduced or initially delivered for introduction into commerce after that date.

(Secs. 201(n), 502, 701(a), 52 Stat. 1041 as amended, 1050–1051 as amended, 1055 (21 U.S.C. 321(n), 352, 371(a)))

Dated: May 4, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: June 2, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-16764 Filed 6-21-82; 8:45 am]

BILLING CODE 4160-01-M

federal register

Tuesday
June 22, 1982

Part III

Environmental Protection Agency

Chemical Information Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 712

[OPTS-82004F; FRL 2039-7]

Chemical Information Rules; Manufacturers Reporting; Preliminary Assessment Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final Preliminary Assessment Information rule requires chemical manufacturers (including certain producers and importers) to submit information on approximately 250 chemicals. The information sought from manufacturers includes data on the quantities of chemicals manufactured, the amounts directed to certain classes of uses, and the potential exposures and environmental releases associated with the manufacturer's own and his immediate customers' processing of the chemicals. The information collected under this rule will answer a critical need for basic data that can be used in setting priorities for testing chemicals and for assessing risks associated with chemicals.

EFFECTIVE DATE: This regulation becomes effective on July 22, 1982.

FOR FURTHER INFORMATION CONTACT: For further information on this rule, or to obtain copies of the Manufacturer's Reporting Form, contact: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-511B, 401 M St., SW, Washington, DC 20460, Toll-free: (800-424-9065), In Washington, DC: (554-1404), Outside the USA: (Operator-202-544-1404).

SUPPLEMENTARY INFORMATION: OMB Control Number: 2000-0420.

I. Introduction

Proposed amendments to this final rule are published elsewhere in this issue of the **Federal Register.**

EPA proposed a rule under section 8(a) of the Toxic Substances Control Act (TSCA) to obtain general use and exposure data on 2,226 chemical substances published in the **Federal Register** of February 29, 1980 (45 FR 13646). More than 150 written comments were received on the proposal and several meetings were held with members of the public. The Agency also received a petition from the Chemical Manufacturers Association requesting that the Agency provide dossiers and other information on the 2,226 chemicals for purposes of public comment. EPA responded to the petition in the **Federal Register** of April 28, 1980 (45 FR 28173). This preamble explains the final rule's provisions and addresses by topic the changes EPA has made to simplify, clarify, and reduce the burden of the rule. A document titled "Responses to Individual Comments" responds to substantive comments individually. This document is available to the public in the administrative record of this rulemaking and is considered to be incorporated by reference here. Some comments are not discussed because changes in the final rule, particularly changes in subject chemicals, have made the issues moot.

After considering comments, the Agency has changed certain provisions and significantly reduced the number of chemicals. The changes to the provisions will reduce the burden of reporting without greatly decreasing the value of the information that the rule will collect on each chemical. Also in response to comments, the Agency has added explanatory material to clarify the requirements. Because of these changes, the Agency has changed the format of the final rule. The rule is now arranged in three Subparts. Subpart A contains general provisions applicable to the entire Part. Subpart B contains reporting requirements for chemical manufacturers. Subpart C will contain the chemical processors' reporting requirements proposed separately today. This arrangement should allow manufacturers and processors to more easily identify the provisions to which they are subject.

Elsewhere in this issue of the **Federal Register,** EPA is proposing three amendments to this final rule. One amendment is the plan for follow-up reporting by processors. Another change would require reporting automatically within 60 days on chemicals recommended for testing under section 4 of TSCA by the Interagency Testing Committee (ITC). The third change would make about 50 additional ITC-recommended chemicals subject to reporting under this rule. These chemicals were listed in ITC reports 5 through 9.

A. Rule Design: Two Part Reporting

The final rule anticipates two rounds of reporting. In the first round, manufacturers of chemicals listed in § 712.30 of the rule must submit Preliminary Assessment Information Manufacturer's Reports. The reports must be submitted to EPA within four months of the effective date of the rule.

The manufacturer's report includes items on the use of a manufacturer's chemical by his customers, when the customers are also processors of the chemical. However, manufacturers may report "unknown" for their processor-customers' uses either when manufacturers do not know the customers' uses to within ±50 percent accuracy, or when the information is subject to a secrecy agreement between the manufacturer and customer.

The Agency will aggregate the customer use data for each chemical. If manufacturers report customer uses unknown for over 20 percent of the total amount of a chemical manufactured and imported, the Agency plans to initiate a second round of reporting, this time by processors, in order to complete its assessments. As noted above, the procedures for this second round of reporting are proposed for comment in a separate notice today.

B. Purpose of the Rule

The information collected under this rule will answer a critical need for basic data that can be used in setting priorities for testing chemicals and for assessing risks associated with chemicals.

For the majority of the chemicals presently listed, ITC has recommended that EPA propose testing rules. Under TSCA section 4, within 12 months of ITC's recommendation, EPA must initiate rulemaking for testing or publish a notice explaining why a test rule is not necessary. Information on potential exposure is needed for the decision. Unfortunately, available exposure information has rarely been adequate for a decision. As a result, EPA has had problems making the decisions required by statute. This rule will allow test rule decisions to be based on more complete and accurate potential exposure data.

A few chemicals on the rule were identified by public notices of substantial risk under TSCA section 8(e). For the listed 8(e) chemicals, EPA does not have sufficient exposure information to determine the extent of risks presented. When this rule provides the exposure data, EPA will be able to evaluate and recommend appropriate action for these 8(e) substantial risk notices.

We have changed the focus of the first edition of the rule to serve only the most immediate needs for assessment of test candidates and 8(e) reports. Therefore, we eliminated from the rule those chemicals proposed for purposes of general problem identification. These include chemicals proposed because of their high production volume, chemicals which the ITC has been unable to completely evaluate because of lack of

exposure data, and a small number of chemicals from other sources described in the notice of proposed rulemaking.

II. Who Must Report

A. Persons Included

1. *Manufacturers.* The term "manufacture" under TSCA includes importing and producing as well as manufacturing activities. Persons must report on each listed chemical substance that they manufactured for commercial purposes in the reporting period specified for the chemical. Discussion of the application of this rule to producers and importers follows.

2. *Producers—Miners and oil refiners.* Questions were asked during the comment period about the application of this rule to mining of chemical substances. The concern was that listed chemical substances are present in mined substances in variable or undefined concentrations and that a single chemical substance may be reported as "manufactured" more than once in the stream of commerce. Commenters felt that it must be made clear precisely at what point they are "manufacturing" a specific chemical substance that is present in a mined substance. We have provided clarification both here and in the rule.

Any method of extraction, refinement, or purification of the mined substance to make it marketable as a listed chemical substance is to be regarded as "manufacture of a listed chemical substance" for the purposes of this rule. An undefined or variable concentration mixture not intended for marketing as a listed chemical is not subject to this rule.

In general terms, mining can be regarded as extracting a substance from the atmosphere, earth, or sea. The most common methods are digging ores and drilling oil. Many persons mine complex substances containing listed chemicals in undefined or variable concentrations, but do not refine the mined substance in order to extract a particular chemical substance for use or sale. Some of the chemicals subject to this rule may be present in and produced from these complex precursor substances. However, because EPA has excluded undefined, variable composition substances from the list of chemicals subject to this rule, production or mining of the undefined, variable composition precursor is not to be reported. Only subsequent steps devoted to production of the listed chemical are reportable.

For example, persons who manufacture a chemical substance such as "sweetened naphtha, 64741–87–3," but do not refine the naphtha to produce "hexane, 110–54–3" would not report on hexane. Only the production of "hexane" as an isolated product must be reported—not previous production of more crude, complex substances such as the naphtha from which hexane is extracted.

3. *Importers.* Persons must report on any chemical substance listed in § 712.30 that they imported in bulk for commercial purposes during the reporting period.

Importers should report chemical substances imported in bulk in any grade of purity, in aqueous solution, or containing additives (such as stabilizers or other chemicals) to maintain the integrity or physical form of the substance. This does not include formulated mixtures of two or more chemicals that are not additives.

The chemicals that must be reported are those that are marketed and used as a chemical listed in § 712.30. Such chemicals were identified by name and CAS number on the Inventory regardless of purity and must be reported for this rule as chemical substances. The additives, for example, are merely to enhance the ability to use the single major component chemical, as with antioxidants. It is still the chemical substance per se that is being marketed and used, and that must be reported for this rule.

EPA interprets TSCA to provide that importers of mixtures are importers of any chemical substance contained in such mixtures. Alternatively, to the extent that such products may technically be considered mixtures as defined under TSCA, EPA has determined that effective enforcement of TSCA requires us to obtain data on such products. This is because a chemical substance in aqueous solution or containing additives is used as the chemical substance per se, and such products may account for a substantial amount of exposure to the chemical.

B. Exemptions From Reporting

Most of the comments supported the exemptions to reporting in the proposed rule. The proposed exemptions have been adopted. In addition, the final rule contains an exemption suggested by commenters to exclude reporting on the manufacture of less than 500 kilograms annually at a plant site. The Agency estimates that this exemption will exclude about 170 reports. Excluding reports of these small production quantities will not affect assessment of the chemicals and so will relieve an unnecessary reporting burden.

III. Reporting Form for Manufacturers

A facsimile of the Manufacturer's Report—Preliminary Assessment Information form appears in § 712.28. The data reporting section of the form (Section IV) has two parts: Part A: Plant Site Activities and Part B: Chemical Substance Processing by Customers. Production, processing, and use at each single domestic manufacturing site must be reported on Part A, including the number of workers, uses, and process types employed, and quantities of the chemical that are or are not recovered. Part B of the form applies to the processing of the chemical by others. Part B will account for the quantity of chemical that is distributed from the manufacturing plant site. Altogether, the form identifies where a chemical is made and in what quantities, how many workers are potentially exposed during manufacture, processing, and use at the manufacturing plant site, what likely environmental releases exist, and what quantities are used in various categories of uses both by the manufacturer and as the chemical moves into commerce.

In Part A, items 1 and 2 ask for total quantities of the chemical imported and domestically manufactured. Item 3 covers quantities lost during manufacture. Items 4, 5, 6, and 7 ask for quantities, worker-hours, and number of workers associated with enclosed, controlled release, and open process categories. Item 4 covers manufacture of the chemical; item 5 covers on-site use as a reactant; item 6 covers on-site non-reactant use; and item 7 covers on-site preparation of products. Item 8 asks how much of the chemical the manufacturer makes into products to be used by industry or by consumers; these products include the chemical itself and mixtures containing the chemical, articles with some release of the chemical possible, and articles with no release. All of the above Part A items concern the manufacturer's own activities and use of his own products.

Part B concerns the activities of the manufacturer's immediate customers (processors). Item 9 parallels item 8 of Part A; it asks how much of the chemical the customer makes into products to be used by industry or by consumers in various forms. Item 10 asks for the trade name(s) under which the manufacturer markets the chemical to his customers. This item is only to be answered if the manfacturer reports that his customers' uses are unknown for more than 20 percent of the quantity of chemical manufactured and imported. Item 11 asks the manufacturer to estimate, based upon his general knowledge of industry practices, the quantity of the chemical that is processed by his customers in enclosed, controlled, or open processes, respectively.

A. Readily Obtainable Data

TSCA section 8(a) authorizes EPA to require information that is "known to or reasonably ascertainable by" the respondent. This is defined at § 712.3(g) as "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden." For purposes of this section 8 rule, the Administrator has determined that a lesser standard should apply.

The rule requires persons to report data that are readily obtainable by management and supervisory employees responsible for manufacturing, processing, distribution, technical services, marketing, and other related activities. These knowledgeable people are responsible for providing estimates and associated accuracy levels for the data elements on the form. The comments supported this standard.

B. Accuracy for Reporting

The proposal discussed options for the accuracy to be required for reporting quantities of a chemical under the rule. As the proposal stated, exact numbers will not be required. We consider that permitting estimates to be reported will provide data sufficient for the purposes of this rule and will make the reporting easier. Comment was requested on various options for the required accuracy. These were: accuracy of ±50 percent for all quantities; accuracy of ±10 percent or ±20 percent on a person's own activities and ±50 percent on others' activities; or allowing respondents to specify the accuracy. We have decided that the accuracy should be related to the activity reported. For most of Part A of the form, dealing with a manufacturer's own activities, estimates must be the best estimates from readily obtainable data, but no specific accuracy range will be required. For items 3b, 3c, and 3d relating to losses during manufacture, accuracy must be specified by the respondent. For Part B of the form, dealing with processor-customers' activities, quantities must be reported within ±50 percent.

We are persuaded that manufacturers must routinely know their own production efficiencies and quantities in order to control their costs and price their products. Thus, when manufacturers report about their own activities, the best estimate from readily obtainable data would be sufficiently accurate. There is no need for the company to expend further effort to report more exactly. For example, it will be legitimate for a company to report figures based on design capabilities of a process. Thus if a process is planned to utilize or produce a certain quantity per "run" or per unit time, or is planned to produce a certain quantity of product from a defined quantity of feedstock material, then the company may assume that the design quantities are the actual quantities, and not attempt to account for variations.

Most of the companies who commented favored the broadest possible limits on accuracy of quantities reported. Except for the questions relating to losses during manufacture and customer activities, companies simply endorsed broad limits without discussion. They cited no specific difficulties in reporting on quantities going into and coming out of their own production processes. One commenter in fact said, "If we do it, we know it." The Agency has concluded that reporting on the basis of readily obtainable data will not impose significant burdens.

Based on review of comments and our intention to ease the reporting burdens, the final rule allows estimates for worker-hours and numbers of workers, as well as for quantities of the chemicals to which workers will be exposed. The estimates for worker-hours and number of workers should be based on readily obtainable data.

Items 3a, 3b, 3c, and 3d deal with losses during manufacture of the chemical. Comments said lack of measured data presented a serious difficulty in meeting the proposed level of accuracy for quantities reported on question 3a. For the final rule, manufacturers may calculate the total loss for question 3a by finding the differences between the quantities theoretically manufactured, and quantities actually used or sold. For items 3b, 3c, and 3d, we have decided to allow respondents to simply tell us the accuracy of the quantities reported. The following difficulties were cited for reporting the destiny of losses: many times the amounts lost are very small, on the order of parts per million, and a 10 percent or 50 percent difference would be insignificant or unmeasurable; routine methods for analyzing emission or effluent amounts do not exist in most cases; and in some cases there are multiple sources of loss that would make calculations extremely difficult. We have concluded that by allowing companies themselves to specify the accuracy of the figures, based on readily obtainable data, we will receive the estimates we need, without imposing unnecessary burdens. Companies are not required to conduct monitoring to comply with this rule; they may answer this item by mass balance estimates.

The accuracy of reporting customer activities under item 9 of the proposed form received the greatest attention from commenters. Most commenters felt that quantities of a chemical processed by individual customers in enclosed, open, or controlled release operations would be beyond their knowledge in most cases. Furthermore, the proposed item 9 asked for quantities of chemicals by customer use and process category in a combined matrix. This simultaneous accounting for quantities would have required a customer-by-customer accounting, followed by sorting and aggregating quantities into 16 matrix boxes. In the view of most companies, this complicated accounting together with their lack of knowledge of customer processes would have resulted in frequent reporting of quantities as "unknown."

We have changed the reporting of customer activities in response to difficulties described in comments. The final form has two items, 9 and 11, to cover customer activities. Item 9 now asks for quantities by customer use within ±50 percent accuracy. Commenters indicated that this could be done. Where respondents cannot report within ±50 percent, or where they have a secrecy agreement with the customer, they may report "unknown." Item 11 now asks for the respondent's estimate of the kinds of processes generally used for the chemical.

In general, manufacturers should report information on their customers' uses to the extent that this information is known. Manufacturers are not required to obtain additional information from customers for this rule.

C. Reporting Worker-Hours, Number of Workers, and Quantities: Items 4–7

As a result of comments, EPA has simplified reporting of worker-hours, number of workers, and quantities by process category under items 4–7. Only the workers directly assigned to the manufacturing, processing, and use of the chemical should be counted. Maintenance workers should be counted only if they are directly assigned to and are a regular part of a process.

When answering the items on worker-hours or number of workers, respondents must (i) identify the process category (enclosed, controlled release, or open) with which the worker spends the most time, and (ii) determine the number of workers involved with a given process category. For multiprocess operations, workers operating more than one process category should be listed

only once—under the process category with which they work most of the time. This should avoid double counting of workers.

Worker-hours need not be calculated from detailed production records, but may be based on design factors. That is, worker-hours may be estimated from the plant's production of a given chemical and the design number of employees needed to achieve that production.

The final rule simplifies reporting by requiring the total number of workers involved in each process category, and deleting the proposed distinction between full and part-time workers. The number of workers should include employee turnover, and will not necessarily correspond to worker-hours. Include all employees who work on a given chemical's production or processing, regardless of the length of time of employment.

Instructions have been clarified regarding items on the quantity of a chemical that goes through each process category. Chemical production could involve a single process or a multiprocess operation, a split stream involving different processes, or two separate streams involving different processes (e.g., one stream might be for a reagent grade chemical and another for a technical grade). The instructions discuss how to handle reporting in these differing circumstances.

D. Preparation and Uses of Manufacturer's Products: Items 7 and 8

The form has been revised to identify more clearly the distinct activity of on-site product preparation (making a product containing the manufactured chemcial). Item 7 in the final rule applies only to plant sites that both manufacture and process a chemical. If a manufacturer of a listed chemical also produces a formulated mixture or other industrial or consumer product containing the chemical, he must report the chemical quantities, number of workers, and process categories in this question.

Item 8 asks for the quantities of the substance incorporated into various use categories of products produced by the manufacturer at the reporting site. This item also incorporates proposed question 12 on export of the chemical substance (as the chemical or as part of a product).

Commenters thought we should differentiate between institutional and industrial uses to better judge exposures. We do not believe that this degree of differentiation will contribute to the evaluation of a chemical without more information on the manner of use of the chemical. Therefore, for the purposes of this rule, "industrial" and "institutional" products are treated in the same manner.

Commenters said the definition of consumer products should have the same exemptions as listed in the Consumer Product Safety Act (15 U.S.C. 2052(a)(1)(D)) (CPSA). We have not adopted this suggestion. Our purpose in citing CPSA is simply to help differentiate between consumer and industrial products. Thus, the CPSA definition, without its exemptions, is included in the rule to guide manufacturers in categorizing their products.

E. Categorizing Uses Under Items 8 and 9

Items 8 and 9 differentiate products into articles containing listed chemicals versus products that are chemical substances or mixtures. Articles are further differentiated into those designed so that there is no release of the chemical during normal use, versus articles that may allow direct user contact with the chemical during normal use. In evaluating exposure potential, chemicals in "articles with no release" will be considered as having potential exposure only during disposal or mishandling of the article.

One commenter said that fabrics with dyestuffs retained on them should be considered as articles containing chemicals. We agree. These would generally be "articles with some release" since the chemical dyestuffs would be in direct contact with the user.

F. Customer Uses: Items 9, 10, and 11

Items 9 and 11 ask the manufacturer to estimate the quantities of the chemical that his customers incorporated into various categories of products, exported, consumed as reactant, and processed by various categories of process. The manufacturer is to base his estimates on his knowledge of the market for the products and his customers' roles in that market.

If manufacturers do not know how all quantities of the marketed chemical are used by customers, or if a use is subject to a secrecy agreement with the customer, the amount may be reported as "unknown". If the manufacturer reports that more than 20 percent of the total quantity manufactured and imported has unknown uses, in question 10 he must provide the trade names under which he marketed the "unknown" amount. The Agency, as discussed below, will use the trade names for processor reporting, if it becomes necessary for that chemical.

G. Follow-up Reporting

Nearly every industry comment requested that EPA eliminate the proposed requirement to submit customer lists for purposes of follow-up reporting on customer data that are unknown to manufacturers. Commenters cited several difficulties with the approach, including their own confidentiality concerns and the burden of making up the lists when there are many customers. In addition, some pointed to the potential burden for all concerned, including EPA, of having follow-up proceed by mailing of letters back and forth. This would be difficult, especially when manufacturers have customer addresses for deliveries rather than addresses for technical contacts.

The Agency sees merit in many of the comments on the proposed approach and is proposing a different one in a separate proposed rule elsewhere in this issue of the **Federal Register**. The separate notice describes the new proposal and discusses the comments already received on processor reporting. In general, under the new approach, the Agency would aggregate the manufacturers' reports on a chemical. If "unknown" uses are reported for more than 20 percent of the aggregate quantity manufactured and imported, the chemical will be the subject of follow-up reporting by processors. The market names for the chemical will be taken from the responses to question 10 of the manufacturers' reporting forms. These names will be published, and processors of the chemicals under these names will report about them. This approach is based on commenters' suggestions that EPA should specify criteria that would trigger follow-up reporting, and that EPA should publish trade names on which processors must report in order to protect the confidentiality of chemical product composition.

H. Time Allowed To Report

For the final rule, we based the time allowed to report on comments, changes in provisions of the rule and form, and the significantly decreased number of chemicals subject to reporting. From available data, we estimate the average and median number of reports for a manufacturing site now to be 2.8 and 2, respectively. The maximum number of reports from any site is expected to be 35; the site with 35 reports has over $1 billion sales annually. Based on these data, four months from the effective date of the rule should allow enough time for reporting.

I. Reporting Period

The Agency received comments saying that records of data to be submitted under this rule are often kept by a corporate fiscal year that does not coincide with the calendar year, and that it would be difficult for these companies to report by calendar year as originally proposed. To reduce this aspect of the reporting burden, EPA has changed the reporting period in the final rule. A company should report a chemical's production during the company's most recent complete corporate fiscal year as of the date the chemical is listed in § 712.30. This is the reporting period referred to in the discussion of reporting requirements for manufacturers. Even though these reporting years may vary somewhat among manufacturers, the disparity will not significantly affect the value of the data for purposes of this rule.

J. Plant Site Reports

In response to comments that it would be burdensome for companies to aggregate data from their plant sites before submitting it to EPA, the final rule now requires a form to be submitted for each plant site. Thus the address of the plant site must now be provided on the form, along with the Dun and Bradstreet number for the plant site when that number exists. The reporting company may decide whether to have headquarters or individual sites complete forms, depending on which is more convenient for the company. This approach also allows EPA to gather data that can be compared to the site-specific data on the Inventory. This comparison will allow the Agency to assess changes in the dimensions of potential exposure, and to consider potential local problems.

A question was raised in the comments about whether a company manufacturing a chemical to order for another company should submit the form or let the buyer submit it. The answer is that the actual manufacturer, not the buyer, should submit the form.

K. Recordkeeping

Commenters expressed concern over the proposed requirement to maintain records that support information submitted to EPA. The proposed five-year retention period was said to be too long and too burdensome. The Agency agrees that this provision should be deleted. The records supporting reporting under this rule will be records that companies will retain as a matter of business. Companies should be alert to the possibility that they may be required to report under this rule in the future and consider or, if necessary, reconsider their recordkeeping practices in that light.

IV. Chemicals Subject to the Rule

The final rule applies to the approximately 250 chemical substances and three categories listed by CAS number in § 712.30. Manufacturers and importers must report on these substances. (An alphabetized list of the chemicals can be requested from the Industry Assistance Office at the telephone number given at the beginning of this notice.) The three categories of chemicals need be considered only by persons who reported confidential chemical identities for the Inventory.

We wish to note that we will use future iterations of this rule to collect information on additional chemicals. One list of additional chemicals is proposed for comment separately in this issue of the **Federal Register.** We are also separately proposing that certain chemicals be placed automatically on the list and that reporting be immediately required on those chemicals without proposal and comment.

Commenters wanted EPA to list the names of all chemicals that must be reported for this rule, and not to list any category names of chemicals. The Agency does not intend that reports be submitted on all chemicals that fall within the listed categories. The purpose of listing the categories is to require reporting on certain chemicals that are confidential on the TSCA Inventory. (Listing the CAS number of a confidential chemical would automatically divulge its identity.) Of the chemicals that fall within listed categories, a manufacturer must report only on the chemicals that he claimed confidential for the TSCA Inventory.

V. Other Issues

A. Small Manufacturers

Section 8(a)(3) of TSCA requires the Administrator to consult with the Small Business Administration and then to prescribe, by rule, standards to determine who may qualify as a small manufacturer or processor. Such small businesses are then exempt from section 8(a) rule requirements. However, if a chemical substance is subject to certain proposed or final actions by the Agency, EPA need not apply the section 8 exemption for small businesses manufacturing or processing the chemical. Among the actions that could remove the small business exemption are proposed rules under section 4, 5, or 6 of TSCA. Although several chemicals in the list published today are subject to section 4 proposals, EPA has decided not to require any reporting by small businesses. The additional data from those companies would not significantly influence the overall preliminary assessments.

For this rule, for a plant site to qualify as small with respect to a listed chemical, a manufacturer or importer must meet both of the following criteria:

i. Total annual sales taken together of all sites owned or controlled by the foreign or domestic parent company were below $30 million for the reporting period.

As chemicals become subject to this rule in the future, the Agency will consider the need to adjust this dollar figure to reflect inflation. Sales figures would be based on activities at all of the plant sites of the reporting firm, its parent, and all subsidiaries owned or controlled by the parent company. The parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock, or other equity rights, or has the power to control the management and policies of the other company.

ii. Total production of the listed substance for the reporting year was below 45,400 kilograms (100,000 pounds) at the plant site.

The EPA has consulted with the Small Business Administration in developing the exemption standard for the rule. The exemption criteria for this rule have not changed from the proposal, except for the addition of a factor to correct the sales cutoff for inflation.

B. Confidentiality

1. *Certification.* Some commenters noted that the effort they would have to spend to substantiate claims of confidentiality by answering the proposed substantiation questions would exceed that spent in answering the substantive questions presented in the form. After considering comments, we have concluded that the method of substantiation outlined in the proposal was overly burdensome and that a simplified method of substantiation should be adopted for this rule.

For the final rule, in order to claim any information on the form as confidential, the respondent must certify, as in the Inventory Reporting Regulations, that the claims of confidentiality are made in good faith and that the four listed statements are true. This simplification will substantially reduce industry's expenditure of time, money, and personnel.

The final reporting form has separate signature blocks for confidentiality certification and for technical accuracy certification. This should alleviate the concerns of commenters who said that an importing subsidary may not be able to certify to confidentiality claims for information supplied by a foreign parent. In this case, the foreign parent can certify regarding confidentiality and the U.S. subsidiary can certify the accuracy of data.

2. *Release of data to the public.* Industry and public interest groups expressed concern as to whether or not EPA planned to publish aggregates of data from this rule or publish only those discrete data items that are not claimed confidential. One public interest group preferred that the Agency release discrete data elements not claimed as confidential. They felt this would aid people in identifying local problems. Industry generally favored publishing aggregates of the data.

There are two purposes for releasing data received by the Agency:

i. To allow the public and the states to conduct local activities to identify and control risk situations, and

ii. To allow public comment on the aggregate data the Agency uses to make its decisions.

The first purpose seems best served by the release of discrete data items that have not been claimed confidential. However, comments indicated most of the reported data will be legitimately claimed to be confidential business information. Therefore, the public would be likely to receive only incomplete data that had not been claimed confidential. Moreover, the release of discrete non-confidential data elements would limit the release of the aggregate data used in risk assessments; discrete non-confidential data could be subtracted from the aggregate to reveal secret data.

Given these considerations, we have decided to release the following types of non-confidential data:

i. Identification of a firm or plant site that manufactures or processes a chemical, except when this fact is confidential.

ii. Aggregate data on production, uses, and workers for each chemical.

It will be necessary for us to withhold some data that have not been claimed confidential in order to protect confidential data within an aggregate. However, the Agency will determine its aggregation method in a manner that will allow as much data as possible to be released, but that will not allow confidential information to be recognized by the public. By releasing aggregate data we will be able to share information with the public, including the regulated industry.

VI. Economic Impact

EPA estimates that chemical manufacturers will spend a maximum of $760,000 to report on the approximately 250 chemicals on this rule.

The fixed costs per plant site to comply with the rule are estimated at $480. This includes time to become familiar with the reporting requirements, and time to determine which listed chemicals the plant site produces. Variable costs of compliance are estimated at an additional $420 per report that must be submitted. The variable costs include time to determine the information required, to determine whether the information should be claimed as confidential, and to complete the form and certification requirements. For the median company, the rule will cost a maximum of about 0.004 percent of its profit. This is not a balance sheet loss, but a theoretical cost based on time the company will spend searching for data.

The fixed and variable cost estimates were based on the number of hours that would be required to complete a form. EPA estimated an average of 18 hours for a site to become familiar with the rule, determine which chemicals to report on, and put together a final package for submittal to EPA. This figure could be lower or higher depending on how many forms are involved. An additional 16 hours were estimated for a site to complete each form. At an average of 3 reports per site, these estimates allow 66 hours (18+(3 × 16)) for an average site's compliance.

TSCA Inventory data show that about 450 plant sites will submit a total of about 1,300 reports. The plant sites represent about 330 companies, for an average of about 4 reports per company.

VII. Rulemaking Record

The administrative record for this rule (docket number OPTS 82004) contains the following documents. All documents, including the index to this public record, are available to the public in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m. weekdays, Rm. E-107, 401 M St., SW., Washington, DC 20460. This record includes basic information considered by the Agency in developing the final rule. The record includes the following information, which is more specifically described in the TSCA Section 8(a) "Level A" Rulemaking Index to the Public Record:

(1) The Advance Notice of Proposed Rulemaking (OTS-82004a), published in the **Federal Register** of June 27, 1979 (44 FR 37517).

(2) Initial Report of the TSCA Interagency Testing Committee published in the **Federal Register** of October 12, 1977 (44 FR 55026).

(3) Written comments to the Advanced Notice of Proposed Rulemaking, numbered 1 through 33 (OPTS-82004a).

(4) Chronologically ordered preproposal comments, minutes, and released drafts, numbered 1 through 15.

(5) The proposed rule, "General Recordkeeping and Reporting Requirement: Preliminary Assessment Information" (OPTS-82004b), published in the **Federal Register** of February 29, 1980 (45 FR 13646).

(6) Petition presented to EPA on March 17, 1980 by the Chemical Manufacturers Association (CMA), and EPA's response, published in the **Federal Register** of April 28, 1980 (45 FR 28173).

(7) Support documents, including:

(a) "Chemical Source List" File, describing the sources and criteria used to select the chemicals for this rule.

(b) High volume criterion, confidential file 20-8020030.

(c) Economic Impact Analysis and references.

(d) "Chemical Use List" and references to its file (OPTS-10001), published in the **Federal Register** of July 25, 1978 (43 FR 32222).

(e) Inter-agency survey by EPA, including all correspondence with other agencies in reference to this rule.

(f) Support documents for final sec. 8(a) "Level A" rule, including inter-, intra-agency, and outside correspondence in reference to this rule.

(8) All written comments to the Proposed Rule (OPTS-82004b).

(9) Telephone comments to the Proposed Rule (OPTS-82004b).

(10) Notices concerning the proposed rule: corrections to the rule published in the **Federal Register** of April 7, 1980 (45 FR 23473), and April 18, 1980 (45 FR 26386), and a notice of public meetings published in the **Federal Register** of April 28, 1980 (45 FR 28176).

(11) Transcripts of public meetings on the Section 8(a) "Level A" Rule.

(12) Miscellaneous agency comments, corrections, and correspondence relating to the rule.

(13) Cross references to test rules developed under TSCA section 4(a).

(14) Any comment received from the Office of Management and Budget during its review of the rule regarding compliance with the Paperwork Reduction Act, or Executive Order 12291.

(15) The document titled "Responses to Individual Comments," which contains Agency responses to comments

on the proposed rule. This document is also considered to be incorporated by reference in this **Federal Register** notice of the final rule.

Additional documents may be added to the Public Record. Within 30 days of the date of publication, please notify us of any errors or omissions in the Public Record. Address all correspondence to:

Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

VIII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this regulation is not major because it does not have an effect of $100 million or more on the economy. It is expected to have a one-time maximum cost to chemical manufacturers of about $760,000. It does not have a significant effect on competition, employment, investment, productivity, innovation, or ability of U.S. based enterprises to compete with foreign-based enterprises in domestic or export markets. This regulation was approved without comment by the Office of Management and Budget (OMB) as required by Executive Order 12291.

The information submitted under this rule will cost manufacturers approximately $3,000 per chemical. It is difficult to put an absolute value on information, but the Agency has experienced costs of $10,000 per chemical for even fruitless searches of general reference sources for exposure information. The information to be reported, general as it is, will be of much greater quality and thus reliability than any data otherwise available. When the information is used by EPA and other Federal agencies to set priorities among chemicals, the rule will benefit the public primarily by identifying chemical hazards and thus allowing reduction of risks to health and the environment. The rule will also save public and private time and expense by directing regulatory attention away from many chemicals of lesser apparent risk. The potential value of the rule's information thus will be much greater than the cost of reporting.

B. Regulatory Flexibility Act

Since this rule was proposed before the effective date of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., the Act's requirements do not apply. However, this rule is consistent with the Act's objectives in that it exempts small businesses from reporting under this rule. EPA consulted with the Small Business Administration, Size Standards Division, in developing this exemption.

C. Paperwork Reduction Act

Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, U.S.C. 3501 et seq., and have been assigned OMB control number 2000–0420.

This rule requires manufacturers of about 250 chemicals to submit a two-page form describing their own and their customers' activities. The data to be submitted will permit EPA to estimate how much of a chemical is made for consumer versus industrial uses, how much is lost to the environment, the number of workers exposed during production and processing, and the degree of that exposure.

The rule provides the minimum information needed to assess the risks of human and environmental exposure to chemicals in U.S. commerce. EPA has chosen 250 of the approximately 55,000 chemicals in U.S. commerce for reporting under this rule.

List of Subjects in 40 CFR Part 712:

Chemicals, Environmental Protection, Reporting and recordkeeping requirements.

Dated: June 7, 1982.

Anne M. Gorsuch,

Administrator.

Therefore, 40 CFR Chapter I is amended by adding a new Part 712 to read as follows:

PART 712—CHEMICAL INFORMATION RULES

Subpart A—General Provisions

Sec.

Subpart B—Manufacturers Reporting—Preliminary Assessment Information

Authority: Sec. 8(a), Toxic Substances Control Act, Pub. L. 94–469 (90 Stat. 2003, 15 U.S.C. 2601 et seq.).

Subpart A—General Provisions

§ 712.1 Scope and compliance.

This Part establishes procedures for chemical manufacturers and processors to report production, use, and exposure-related information on listed chemical substances. Subpart A establishes requirements that apply to all reporting under this Part. Subparts B and C, respectively, cover manufacturers' and processors' reporting.

§ 712.3 Definitions.

The definitions in section 3 of TSCA, 15 U.S.C. 2602, apply for this Part. In addition, the following definitions apply:

(a) "Byproduct" means any chemical substance or mixture produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

(b) "EPA" means the U.S. Environmental Protection Agency.

(c) "Import in bulk form" means to import a chemical substance (other than as part of a mixture or article) in any quantity, in cans, bottles, drums, barrels, packages, tanks, bags, or other containers used for purposes of transportation or containment, if the chemical substance has an end use or commercial purpose separate from the container.

(d) "Importer" means anyone who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the U.S. and includes the person liable for the payment of any duties on the merchandise, or an authorized agent on his behalf. Importer also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20.

(4) The transferee, if the right to withdraw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR Part 144. For the purposes of this definition, the customs territory of the U.S. consists of the 50 states, Puerto Rico, and the District of Columbia.

(e) "Impurity" means a chemical substance unintentionally present with another chemical substance or mixture.

(f) "Intermediate" means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of

other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions. (See also paragraph (j) of this section.)

(g) "Known to or reasonably ascertainable by" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden.

(h) "Manufacture for commercial purposes" means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer and includes, among other things, such "manufacture" of any amount of a chemical substance or mixture:

(1) For commercial distribution, including for test marketing.

(2) For use by the manufacturer, including use for product research and development, or as an intermediate.

Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts and coproducts that are separated from that other substance or mixture, and impurities that remain in that substance or mixture. Byproducts and impurities may not in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical produced for a commercial purpose.

(i) "Mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that "mixture" does include (A) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are included in the EPA, TSCA Chemical Substance Inventory after the effective date of the premanufacture notification requirement under 40 CFR Part 720, and (B) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water. The term mixture includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.

(j) "Non-isolated intermediate" means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. (See also paragraph (f) of this section.)

(k) "Owned or controlled by the parent company" means the parent owns or controls 50 percent or more of the other company's voting stock or other equity rights, or has the power to control the management and policies of the other company.

(l) "Person" means any natural person, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency, or instrumentality of the Federal government.

(m) "Process for commercial purposes" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(n) "Site" means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site.

(o) "Test marketing" means distributing in commerce a limited amount of a chemical substance or mixture, or article containing such substance or mixture, to a defined number of potential customers, during a predetermined testing period, to explore market capability prior to broader distribution in commerce.

(p) "TSCA" means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

§ 712.5 Method of identification of substances for reporting purposes.

(a) *Report on TSCA-regulable quantities.* Unless specifically otherwise required, respondents must report only about quantities of a chemical that is defined as a chemical substance under TSCA section 3(2).

(b) *Chemicals from natural sources.* A manufacturer of a chemical substance which is extracted from an ore, from oil, or from any other natural source must report only about the manufacturing steps for, and the uses of, that chemical, not about production of the natural source material or other crude precursors derived from the natural source material.

For example, persons who manufacture a chemical substance such as "sweetened naphtha, 64741-87-3," but do not refine the naphtha to produce "hexane, 110-54-3" would not report on hexane. Only the production of "hexane" as an isolated product must be reported—not previous production of more crude, complex substances such as naphtha from which hexane is extracted. Thus, persons who produce crude oil, ores, and other crude natural materials, but do not carry them through further manufacturing steps that produce a listed chemical have no reporting responsibilities under this Part. Note, however, that any method of extraction, refinement, or purification of a listed chemical substance is considered to be manufacturing for the purposes of this rule.

(c) *Chemical substances as marketed.* This Part requires reporting about chemical substances as they are marketed or used in practice. The following preparations of a chemical substance must be reported as the substance itself, not as a mixture, since these preparations are regarded as the substance in practice.

(1) The chemical substance in aqueous solution.

(2) The chemical substance containing an additive (such as a stabilizer or other chemical) to maintain the integrity or physical form of the substance.

(3) The chemical substance in any grade of purity.

§ 712.7 Report of readily obtainable information for Subparts B and C.

TSCA section 8(a) authorizes EPA to require persons to report information that is known to or reasonably ascertainable by them. For purposes of Subparts B and C, however, a lesser standard applies. Companies must report information that is readily obtainable by management and supervisory employees responsible for manufacturing, processing, distributing, technical services, and marketing. Extensive file searches are not required.

§ 712.15 Confidentiality.

(a) Any person submitting information under this Part may assert business confidentiality claims for the information as described in the pertinent reporting form and its instructions. Any information covered by a claim will be disclosed by EPA only as provided in the procedures set forth at 40 CFR Part 2.

(b) Persons must certify to the validity of a claim of confidentiality they make for information reported under this Part, as specified on the reporting form.

(c) If no claim accompanies the information at the time it is submitted to EPA or if certification as to the claim is not made on the reporting form, EPA may place the information in an open file available to the public without further notice to the submitter.

Subpart B—Manufacturers Reporting—Preliminary Assessment Information

§ 712.20 Manufacturers and importers who must report.

Except as described in § 712.25, at the time a chemical substance is listed in § 712.30, the following persons must submit the "Manufacturer's Report—Preliminary Assessment Information" (as described in § 712.28) for each plant site at which they manufactured or imported the chemical substance during the reporting period specified in § 712.30:

(a) Persons who manufactured one or more of the chemical substances listed in § 712.30 for commercial purposes.

(b) Persons who imported in bulk form one or more of the chemical substances listed in § 712.30 for commercial purposes.

§ 712.25 Exempt manufacturers and importers.

(a) Persons who manufactured or imported the chemical substance during the reporting period, solely for purposes of scientific experimentation, analysis, or research, including research or analysis for product development, are not subject to reporting under § 712.20.

(b) Persons who, during the reporting period, manufactured or imported fewer than 500 kilograms (1100 pounds) of the chemical substance at a single plant site are not subject to reporting for that site under § 712.20.

(c) Persons who qualify as small manufacturers or importers in respect to a specific chemical substance listed in § 712.30 are exempt. However, this exemption does not apply with respect to any chemical in § 712.30 designated by an asterisk. A manufacturer is qualified as small and is exempt from submitting a report under this Subpart for a chemical substance manufactured at a particular plant site if both of the following criteria are met:

(1) Total annual sales taken together of all sites owned or controlled by the foreign or domestic parent company were below $30 million for the reporting period;

(2) Total production of the listed substance for the reporting period was below 45,000 kilograms (100,000 pounds) at the plant site.

(d) Persons are not subject to reporting under § 712.20 if they manufactured or imported the chemical substance during the reporting period only in the following forms:

(1) As a byproduct that was not used or sold or that was formed as described in 40 CFR 710.4(d) (3) through (7).

(2) As a non-isolated interimediate.

(3) As an impurity.

§ 712.28 Form and instructions.

(a) Manufacturers and importers subject to this Subpart must submit a single EPA Form No. 7710–35, "Manufacturer's Report—Preliminary Assessment Information," for each plant site manufacturing or importing a chemical substance listed in § 712.30.

(b) Reporting companies may submit their reports through individual plant sites or company headquarters as they choose. A separate form must be submitted for each plant site manufacturing the chemical substance.

(c) Forms must be sent to: Document Control Officer, Office of Pesticides and Toxic Substances, Environmental Protection Agency, P.O. Box 2080, Rockville, MD 20852.

(d) Instructions and a facsimile of the form are as follows:

BILLING CODE 6560-50-M

INSTRUCTIONS FOR MANUFACTURER'S REPORT FORM PRELIMINARY ASSESSMENT INFORMATION

What chemicals to report — This form applies to chemical substances that are listed in 40 CFR 712.30.

Reporting period — Enter the months and years beginning and ending the 12-month period for which you report. This reporting period is listed with the chemical substance in 40 CFR 712.30.

Who must report — Manufacturers and importers must report. See 40 CFR 712.25 for exemptions from reporting.

How many forms to complete — For each chemical, complete a separate form for each plant site that manufactured the chemical.

If a site manufactured and imported the chemical, report both manufacture and import data for the site on a single form.

A company that imported the chemical, but did not process the imported quantity or manufacture an additional quantity, may submit a separate form for each import site or may submit a single form with the total data for all import sites.

Who may submit forms — Companies may choose to complete and submit forms to EPA from each plant site directly, or through company headquarters.

Retention of forms — You should keep a copy of each completed form. Refer to the preprinted Control Number (shown in the upper right corner on the front of the form) when communicating with EPA.

EPA assistance — For further information or to obtain copies of the Manufacturer's Report form, contact:

Industry Assistance Office (TS-799)
Office of Pesticides and Toxic Substances
Environmental Protection Agency
401 M Street, SW.
Washington, D.C. 20460
Toll free: (800) 424–9065
In Washington, D.C.: 554–1404
Outside the USA: Operator (202) 554–1404

I. CERTIFICATION

Technical certification — Certify the technical accuracy of data you report on the form by signing and dating the Technical Certification Statement. Print or type the name and title of the person who signs this statement.

Confidentiality certification — You may claim information confidential by marking appropriate boxes in sections III and IV. If you claim any information confidential, you must certify that the Confidentiality Statements are true for all information claimed confidential on the form. Do this by signing and dating the Confidentiality Certification Statement. Print or type the name and title of the person who signs this statement.

II. CHEMICAL IDENTIFICATION *(Complete A or B)*

Item A — If you are reporting on a chemical that has its CAS Number and Chemical Name listed in 40 CFR 712.30, enter the CAS Number and first fifteen (15) characters of the listed Chemical Name.

Enter N/A in section II, part B, in the spaces for Category Name and Inventory Form C Number.

Item B — If you are reporting a confidential chemical that is in a category listed in 40 CFR 712.30, enter the Category Name as listed, and enter the number of the Inventory Reporting Form C on which you reported the chemical for the TSCA Inventory. (If the Inventory Form C Number is not available, contact the Industry Assistance Office.)

In section II, part A, enter N/A in the spaces for CAS Number and Chemical Name.

III. RESPONDENT IDENTIFICATION

Confidentiality — Mark this box to claim confidential all Respondent Identification in section III. Note that you may not claim your identity confidential if you reported this chemical for the Inventory and did not claim your identity confidential at that time.

Item A — Enter the name, physical location address, and Dun and Bradstreet number of the plant site for which the data are reported.

If your company imported but did not further process or manufacture additional chemicals, and you choose to submit data for all import sites on a single form, enter N/A.

If the plant site does not have a Dun and Bradstreet number, enter N/A in that space.

Item B — Mark the appropriate box to show whether the plant site or corporate headquarters is submitting this form. Enter the corresponding name and mailing address.

If corporate headquarters submits this form, enter its Dun and Bradstreet number. If it does not have a Dun and Bradstreet number, or if the plant site submits this form, enter N/A in the space for Dun and Bradstreet number.

EPA will send all correspondence regarding the form to this address.

Item C — Enter the name, title, and telephone number (including area code) of a person for EPA to contact if there are questions about data reported on this form.

Item D — EPA will acknowledge receipt of the form to the person named in this item.

IV. PRELIMINARY ASSESSMENT INFORMATION

TSCA Regulable Quantities — Except under items 4 and 5, do not report any quantity of chemical substance that is manufactured or processed solely for use as: a pesticide; tobacco or any tobacco product; any source material, special nuclear material, or byproduct material (as terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act); firearms or ammunition; or food, food additives, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug and Cosmetic Act). The above are not TSCA regulable.

Some chemical substances are manufactured for both TSCA and non-TSCA regulable purposes. Thus, under items 4 and 5, include total production of the chemical stream for both TSCA and non-TSCA regulable quantities.

PART A: PLANT SITE ACTIVITIES

Accuracy — For each item, provide numbers that represent your best estimates based on readily obtainable data.

Item 1 — Enter the total quantity of the chemical substance imported in bulk during the reporting period. If you import, but do not further process the imported quantity or manufacture an additional quantity, answer this item and part B only.

Item 2 — Enter the quantity of chemical domestically manufactured during the reporting period, not counting the losses reported in item 3a.

Items 3a–3d — In 3a, report the total quantity lost in manufacture of the substance during the reporting period. Report only routine losses. Do not report unusual spills or accidents. In calculating estimates for quantities not recovered you may: (1) use measured losses, if available, or emission factors and other calculated releases from individual sources; or, (2) if these are not available, or only account for a portion of the total loss, you may make a simple mass balance estimate of expected yield minus actual yield, where actual yield is the value reported in item 2. This quantity in 3a should then be broken down into the three categories below (i.e., 3b + 3c + 3d = 3a). Specify the accuracy you report for 3b, 3c, and 3d, e.g., 1000 kg ± 30%.

3b. Quantity lost to the environment — This covers fugitive emissions to the atmosphere and other losses not described in 3c and 3d.

3c. Quantity in wastes treated to destroy the chemical.

3d. Quantity in wastes not treated to destroy the chemical — This includes, for example, any quantity disposed of in any landfill, surface impoundment, municipal sewage, or storage.

Items 4–7 — Items 4–7 in part A require you to describe the manufacturing process and your use of the chemical in terms of the number of workers and quantity of substance associated with three process categories. Three process categories are described below, followed by instructions for calculating quantities, worker-hours, and number of workers. Additional instructions concerning items 4 through 7 are also listed.

PROCESS CATEGORIES

Enclosed Process — The process is designed and operated so that there is no intentional release of the chemical. In this process category, only fugitive or inadvertent releases occur and special measures are taken to prevent worker exposure and environmental contamination. "Special measures" refer to procedures and equipment that are monitored and used to prevent worker exposure, and scrubbers and other recovery equipment employed to prevent environmental release. Equipment with emergency pressure relief venting would be allowed in this category; routine venting would not. With regard to handling the manufactured chemical, persons who handle closed packages containing the material would be counted under "enclosed process." Persons who package or transfer the unpackaged chemical would be counted in one of the following categories.

Controlled Release Process — The process is operated in a controlled manner to minimize release of the chemical into the workplace. Releases should generally be within prescribed limits. These limits may be dictated by government regulations or by company guidelines. If the chemical is vented outside the plant, the process is a "controlled release" process. Do not count general space ventilation fans.

Open Process — The chemical is routinely in direct contact with the atmosphere (workplace or outside the plant) and no measures are taken to prevent release. For example, reaction vessels are open vats, the chemical is transported or stored in open containers, or the chemical is freely vented into the workplace atmosphere.

QUANTITIES

Process Category — Enter the greatest quantity that is processed in each process category. If there is more than one process stream, calculate each stream separately and then add the values for each process category. If a quantity of the chemical passes in series through an enclosed process and then passes through an open process, the same quantity would be reported twice, once under each process category. (The sum of these quantities may be greater than 100% of the total quantity manufactured.)

Example 1 — A company manufactures technical grade chemical x in four steps.

350,000 kg →	350,000 kg →	350,000 kg →	200,000 kg
Open	Enclosed	Open	Enclosed

The company would report:

Enclosed	350,000 kg
Controlled release	0
Open	350,000 kg

Example 2 — A company produces the same chemical in a reagent and technical grade with the following steps.

Technical Grade Process:

350,000 kg →	350,000 kg →	350,000 kg →	200,000 kg
Open	Enclosed	Open	Enclosed

Reagent Grade Process:

650,000 kg →	500,000 kg →	500,000 kg →	400,000 kg
Controlled Release	Controlled Release	Open	Open

The company would report:

Enclosed	350,000 kg
Controlled release	650,000 kg
Open	850,000 kg

(The open process amount is the total of the maximum quantity in the open process category from each grade.)

Total Quantity – For items 5, 6, and 7, enter the total quantity processed in all process categories. (This total may be less than the sum of the quantities reported in individual process categories.)

WORKER-HOURS

Worker-hours may be calculated for a given process category by multiplying the average number of full-time employees needed for the operation by the number of hours operating annually. Alternatively, worker-hour information may be taken from preexisting information sources such as resource planning or budget figures.

WORKERS

In reporting number of workers for each process category, count the total number of persons directly involved in manufacturing, processing, and handling the chemical during the reporting period. Count maintenance or inspection workers only if they work with the process on a routine basis. Do not count administrative staff.

Three process categories are described in the form: enclosed, controlled release, and open. A worker should be counted as working with only one process category. If he operates several process types, count him under the one with which he spends the most time. If he spends an equal amount of time with several, count him under the most open process.

Example 3 – A company manufactured 1,000,000 kg of a chemical substance in 1980. It manufactured the chemical for all twelve months of the year and did so in an enclosed process.

In order to run the production line, ten (10) workers were present working 40 hour weeks; thus over the course of the year 20,800 worker-hours were used to run the production line.

Over the course of the year, twelve (12) different workers worked on the production of the chemical.

The form would then be filled out as follows:

Process category	Quantity (kg)	Worker-hours	Total workers
Open	0	0	0
Controlled release	0	0	0
Enclosed	1,000,000 kg	20,800	12

Example 4 – A company manufactured 1,000,000 kg of a chemical substance in 1980. It manufactured the chemical for the entire year in a 24 hour/day process consisting of three steps in the open, controlled release, and open process categories. The production line was shut down for maintenance for 2 weeks of the year. The production line had three 8-hour shifts. Each shift in step 1 required 5 workers, while 7 and 10 workers were needed per shift in steps 2 and 3, respectively. The total worker-hours required for each step follows:

Process category	(Shifts/day x hours/shift x workers x days/week x weeks/year)	Workers-hours
Open (Step 1)	(3 x 8 x 5 x 7 x 50)	42,000
Controlled (Step 2)	(3 x 8 x 7 x 7 x 50)	58,800
Open (Step 3)	(3 x 8 x 10 x 7 x 50)	84,000

Analysis of the personnel records showed that a total of 75 individuals worked on the production of the chemical during 1980. After examining the personnel records, the company was able to fill in the following table:

Process category	Total workers
Open (Step 1)	21
Controlled (Step 2)	19
Open (Step 3)	35
	75

Note that workers are not double counted or "split" even though some jobs may require moving from one step of the process to another step of the same process. An employee working on both step 1 and step 2 is counted only in step 1 if he/she spends most of his time at that step. After adding together steps in the same process category, the company would report as follows:

Process category	Quantity (kg)	Worker-hours	Total workers
Open	1,000,000	126,000	56
Controlled release	1,000,000	58,800	19
Enclosed	0	0	0

Item 4 – This item applies to the manufacture of the chemical substance and includes all steps to ready the chemical for further processing or use.

Item 5 – This item applies to use of the chemical at your plant site as a reactant in the manufacture of another chemical substance, where the molecular structure of the chemical is altered by breaking chemical bonds or making new chemical bonds between the original substance and some other substance. Report on all processing up to and including the actual reaction step and any ancillary steps which recycle unreacted chemicals back to the reactor vessel. Do not report on subsequent activities in this question.

Item 6 – Report the quantity of the chemical substance that you use on site. Examples include cleaning solvents, dielectric fluids, emulsifiers, and lubricants. Do not include any quantity that you react to make a product.

Item 7 – Report the quantity of the chemical substance that you process at the manufacturing site into products for on site use or sale. (Note that this does not include manufacture of the chemical substance; this is reported in item 4 above.) This item does include the quantity of chemical substance that you incorporate in a mixture or article. Report the steps up to and including incorporation of the chemical into an article; do not include any further processing of the article.

Item 8 – Report the quantity of the chemical substance that you prepare for commercial distribution in each of the product types in 8a to 8g. Do not include any quantity of chemical substance that your customers will further process. This will be reported in item 9.

In items 8a to 8f, report the quantity of the chemical substance in products that are for domestic use. If you are uncertain about whether your products are for domestic or foreign use, report them as domestic.

The products are divided into industrial and consumer products. "Industrial" means the manufacturing and service industries covered by the Standard Industrial Codes. Products meant to be used primarily by the general population are considered to be "consumer" products. The following definition from the Consumer Product Safety Act can be used as a guide (15 U.S.C. 2052(a)(1)): "The term 'consumer product' means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in

recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise." If you are uncertain about whether your products are industrial or consumer, report them as consumer.

Three types of industrial and consumer product types are described below.

"Chemical substance or mixture" means a chemical, or mixture containing the chemical, that is used directly by the persons using the product, e.g., cleaners, paints, inks, deodorizers, solvents, etc. This includes chemicals or mixtures in containers or other articles whose purpose is to release the chemical (e.g., cans of spray paint, ink pens, and other applicators).

"Articles or products with no release" are articles constructed to prevent human exposure to or release to the environment of the chemical substance during normal use and storage (e.g., chemical coatings on internal components, and chemicals inside sealed articles as in thermometers and batteries).

"Articles or products with some release" are articles whose material components are made of chemicals which come in direct contact with persons using the article, the atmosphere, land, or water; e.g., exposure can come from leaching, evaporation, or surface contact. This includes such articles as plastic containers, chemically treated textiles, printed paper, coated appliances, etc. If the chemical itself is sold in a bottle or other container it should be reported under "Chemical substance or mixture," not as an article. Only the container itself is an article for purposes of this form; the substance it contains is not a component of an article.

In item 8g, report the quantity of chemical substance that you export directly either as the chemical or contained in mixtures or articles.

Item 9 – Estimate the quantity of the chemical substance that your customers process for each of the uses listed in items 9a to 9h. (Do not include the quantity of chemical substances that your customers will use without further processing; that quantity should be reported in item 8a or 8d.)

For items 9a to 9g, follow the same directions as for items 8a to 8g.

For item 9h, report the quantity of chemical substance that your customers will react to make products that do not contain the chemical substance itself.

For item 9i, report the quantity of chemical substance for which your customers' uses are unknown.

Report your best estimate for items 9a to 9h within ±50%. If you cannot estimate an item to this degree of accuracy, include the quantity in item 9i. You may report "unknown" if the data would reveal information subject to a confidentiality agreement between you and your customers.

Item 10 – If you report your customers' uses as unknown (item 9i above) for more than 20% of the total quantity that you manufacture and import (items 1 and 2 above) list the names under which you distribute the chemical substance.

This item will allow EPA, if necessary, to find out about chemical uses you have reported as "unknown" by requiring processors of your products to report directly to us.

Item 11 – This item addresses your general knowledge of the process types your customers use to process the chemical. Estimate the quantity of the chemical that your customers process in each of the three process categories. Specify "unknown" if you do not know to within ±50%.

IMPORTANT: Before completing this form, please read the accompanying instructions carefully. O.M.B. No. 2000-0420: Approval Expires 3/31/84

EPA U.S. ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

MANUFACTURER'S REPORT PRELIMINARY ASSESSMENT INFORMATION

This information is required under the authority of Section 8(a), Toxic Substances Control Act, 15 U.S.C. 2607.

When completed send this form to:
Document Control Officer
Office of Pesticides and Toxic Substances
U.S.E.P.A.
P.O. Box 2080
Rockville, Md. 20852

CONTROL NUMBER

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FROM: Mo. | Yr. | TO: Mo. | Yr.

Section I — CERTIFICATION

TECHNICAL CERTIFICATION STATEMENT

I hereby certify that, to the best of my knowledge and belief, all information entered on this form is complete and accurate. I agree to permit access to, and the copying of records by, a duly authorized representative of the EPA Administrator, in accordance with the Toxic Substances Control Act, to document any information reported here.

Signature | Date

Name and title — *Please print or type*

CONCERNING EPA DISCLOSURE OF INFORMATION

Any person who submits information to EPA under the Preliminary Assessment Information Rule (40 CFR 712) should be aware of EPA regulations (40 CFR Part 2) which govern disclosure of such information. Those regulations provide that such person may, if he or she desires, assert a confidentiality claim covering part or all of the information submitted. Information covered by such a claim will be publicly disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. However, if no such claim accompanies the information when it is received, EPA may make that information public without notifying the submitter.

CONFIDENTIALITY STATEMENTS

Information disclosed to EPA on this form may be claimed confidential by marking the appropriate boxes below. The person signing the Confidentiality Certification Statement attests to the truth of the following four statements concerning all information that is claimed confidential. Note that chemical substance identity may not be claimed confidential for this rule.

1. My company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.
2. The information is not, and has not been, reasonably obtainable without our consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).
3. The information is not publicly available elsewhere.
4. Disclosure of the information would cause substantial harm to our competitive position.

CONFIDENTIALITY CERTIFICATION STATEMENT

I hereby certify that the Confidentiality Statements on this form are true as to that information below for which I have asserted a confidentiality claim.

Signature | Date

Name and title — *Please print or type*

Section II — CHEMICAL IDENTIFICATION

Part A

CAS No. | | | | | — | | | — | |

Chemical name (first 15 characters)

Part B

Category name (first 15 characters)

Inventory Form C number

Section III — RESPONDENT IDENTIFICATION

☐ *MARK THIS BOX TO CLAIM THIS SECTION CONFIDENTIAL*

Part A — Plant Site — Physical location

Name

Number and street

City

County

State | ZIP code

Dun and Bradstreet number

Part B — Mailing Address of:

☐ Corporate Headquarters ☐ Plant Site

Name

Number and street

City

State | ZIP code

Dun and Bradstreet number (for corporate headquarters only)

Part C — Technical Contact

Name and title

Telephone *(Area code/number)*

☐ At headquarters

☐ At plant site

Part D — Acknowledgement

EPA will send acknowledgement to — *Name and title*

EPA Form 7710-35

Section IV — PRELIMINARY ASSESSMENT INFORMATION

NOTE Mark the box to the left of any item below to claim the answer to the item as confidential. Report all quantities in kilograms (1 kilogram = 2.2 pounds). Enter N/A for any item that does not apply to you; do not leave any blanks.

Part A — Plant Site Activities — *Information in part A must be your best estimate from readily obtainable data. For items 3b, 3c, and 3d, specify the accuracy of your answers.*

☐ 1. Total quantity imported	kg	☐ 2. Quantity manufactured for sale or use	kg
☐ 3 a. Quantity lost during manufacture *(3b + 3c + 3d must equal 3a)*	kg	3 c. Quantity in wastes treated to destroy the chemical	kg ± %
3 b. Quantity lost to the environment	kg ± %	3 d. Quantity in wastes not treated to destroy the chemical	kg ± %

Activity (1)	Process category (2)	Quantity (kilograms) (3)	Total worker-hours (4)	Total workers (5)
☐ 4. Manufacture of the chemical	a. Enclosed			
	b. Controlled release			
	c. Open			
☐ 5. On-site use as reactant	a. Enclosed			
	b. Controlled release			
Total Quantity _____ kg	c. Open			
☐ 6. On-site nonreactant use of the chemical substance	a. Enclosed			
	b. Controlled release			
Total Quantity _____ kg	c. Open			
☐ 7. On-site preparation of products	a. Enclosed			
	b. Controlled release			
Total Quantity _____ kg	c. Open			

☐ 8. MANUFACTURER'S PRODUCTS — Report the quantity of the chemical substance that you prepare for each of the following.

INDUSTRIAL PRODUCTS (domestic)	a. Chemical or mixture	kg	**CONSUMER PRODUCTS (domestic)**	d. Chemical or mixture	kg
	b. Article with some release	kg		e. Article with some release	kg
	c. Article with no release	kg		f. Article with no release	kg
g. Products for export →		kg			

Part B — Chemical Substance Processing by Customers — *Information in part B must be accurate to within ± 50%.*

☐ 9. CUSTOMERS' USES AND PRODUCTS — Estimate the quantity of the chemical substance that your customers use or prepare for each of the following.

INDUSTRIAL PRODUCTS (domestic)	a. Chemical or mixture	kg	**CONSUMER PRODUCTS (domestic)**	d. Chemical or mixture	kg
	b. Article with some release	kg		e. Article with some release	kg
	c. Article with no release	kg		f. Article with no release	kg
g. Products for export →		kg			
h. Quantity of chemical consumed as reactant →		kg			
i. Unknown customer uses →		kg			

☐ 10. MARKET NAMES — If you report your customers' uses as unknown (9i above) for more than 20% of the total quantity of chemical substance that you manufacture and import (20% of items 1 and 2 above), list the market names under which you distribute the chemical. (If you need more space, attach an additional sheet.)

a.	c.
b.	d.

☐ 11. CUSTOMERS' PROCESS CATEGORIES — Based on your knowledge of general industry practices, estimate the quantity of chemical substance that you sell to customers as the chemical and that your customers further process in each of the following categories.

a. Enclosed processes	kg	c. Open processes	kg
b. Controlled release processes	kg	d. Unknown	kg

EPA Form 7710-35

BILLING CODE 6560-50-C

§ 712.30 Chemical lists and reporting periods.

(a) Persons subject to this Subpart must submit a Preliminary Assessment Information Manufacturer's Report for each chemical substance or designated mixture listed below. The information in each Manufacturer's Report for a given substance or mixture must cover the respondent's latest complete corporate fiscal year as of the effective date when the substance or mixture becomes subject to this Subpart. The effective date will be 30 days after the Office of Toxic Substances publishes a notice in the **Federal Register** making the substance or mixture subject to this subpart.

(b) Except as provided in paragraph (c) of this section, chemical substances and designated mixtures will be added after a notice of proposed amendment of this Subpart is published in the **Federal Register**. There will be a 30 day public comment period on each notice; after consideration of the comments, a final amendment will identify the substances and mixtures added.

(c) [Reserved]

(d) A Preliminary Assessment Information Manufacturer's Report must be submitted by November 19, 1982 for each chemical substance listed below.

CAS No., Chemical Name

64-67-5 Sulfuric acid, diethyl ester
71-55-6 Ethane, 1,1,1-trichloro-
72-57-1 2,7-Naphthalenedisulfonic acid, 3,3'-[(3,3'-dimethyl[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
74-87-3 Methane, chloro-
75-05-8 Acetonitrile
75-09-2 Methane, dichloro-
75-12-7 Formamide
75-21-8 Oxirane
75-38-7 Ethene, 1,1-difluoro-
75-56-9 Oxirane, methyl-
77-47-4 1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-
77-78-1 Sulfuric acid, dimethyl ester
77-83-8 Oxiranecarboxylic acid, 3-methyl-3-phenyl-, ethyl ester
78-30-8 Phosphoric acid, tris(2-methylphenyl) ester
78-32-0 Phosphoric acid, tris(4-methylphenyl) ester
78-33-1 Phenol, 4-(1,1-dimethylethyl)-, phosphate (3:1)
78-59-1 2-Cyclohexen-1-one, 3,5,5-trimethyl-
78-87-5 Propane, 1,2-dichloro-
78-93-3 2-Butanone
79-06-1 2-Propenamide
80-62-6 2-Propenoic acid, 2-methyl-, methyl ester
81-21-0 2,4-Methano-2H-indeno[1,2-b:5,6-b']bisoxirene, octahydro-
84-61-7 1,2-Benzenedicarboxylic acid, dicyclohexyl ester
84-66-2 1,2-Benzenedicarboxylic acid, diethyl ester
84-74-2 1,2-Benzenedicarboxylic acid, dibutyl ester
85-68-7 1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester
85-70-1 1,2-Benzenedicarboxylic acid, 2-butoxy-2-oxoethyl butyl ester
87-61-6 Benzene, 1,2,3-trichloro-
87-68-3 1,3-Butadiene, 1,1,2,3,4,4-hexachloro-
88-74-4 Benzenamine, 2-nitro-
89-63-4 Benzenamine, 4-chloro-2-nitro-
90-13-1 Naphthalene, 1-chloro-
92-49-9 Benzenamine, N-(2-chloroethyl)-N-ethyl-
92-52-4 1,1'-Biphenyl
95-39-6 2-Propenoic acid, bicyclo[2.2.1]hept-5-en-2-ylmethyl ester
95-47-6 Benzene, 1,2-dimethyl-
95-48-7 Phenol, 2-methyl-
95-49-8 Benzene, 1-chloro-2-methyl-
95-50-1 Benzene, 1,2-dichloro-
95-51-2 Benzenamine, 2-chloro-
95-54-5 1,2-Benzenediamine
95-63-6 Benzene, 1,2,4-trimethyl-
95-76-1 Benzenamine, 3,4-dichloro-
95-82-9 Benzenamine, 2,5-dichloro-
95-94-3 Benzene, 1,2,4,5-tetrachloro-
96-05-9 2-Propenoic acid, 2-methyl-, 2-propenyl ester
96-08-2 7-Oxabicyclo[4.1.0]heptane, 1-methyl-4-(2-methyloxiranyl)-
96-09-3 Oxirane, phenyl-
96-12-8 Propane, 1,2-dibromo-3-chloro-
96-33-3 2-Propenoic acid, methyl ester
97-02-9 Benzenamine, 2,4-dinitro-
97-63-2 2-Propenoic acid, 2-methyl-, ethyl ester
97-86-9 2-Propenoic acid, 2-methyl-, 2-methylpropyl ester
97-88-1 2-Propenoic acid, 2-methyl-, butyl ester
97-90-5 2-Propenoic acid, 2-methyl-, 1,2-ethanediyl ester
98-07-7 Benzene, (trichloromethyl)-
98-87-3 Benzene, (dichloromethyl)-
98-88-4 Benzoyl chloride
98-95-3 Benzene, nitro-
99-09-2 Benzenamine, 3-nitro-
99-30-9 Benzenamine, 2,6-dichloro-4-nitro-
99-56-9 1,2-Benzenediamine, 4-nitro-
100-01-6 Benzenamine, 4-nitro-
100-41-4 Benzene, ethyl-
100-42-5 Benzene, ethenyl-
100-44-7 Benzene, (chloromethyl)-
101-43-9 2-Propenoic acid, 2-methyl-, cyclohexyl ester
101-77-9 Benzenamine, 4,4'-methylenebis-
101-90-6 Oxirane, 2,2'-[1,3-phenylenebis(oxymethylene)]bis-
103-11-7 2-Propenoic acid, 2-ethylhexyl ester
103-71-9 Benzene, isocyanato-
105-16-8 2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester
106-40-1 Benzenamine, 4-bromo-
106-42-3 Benzene, 1,4-dimethyl-
106-44-5 Phenol, 4-methyl-
106-46-7 Benzene, 1,4-dichloro-
106-47-8 Benzenamine, 4-chloro-
106-50-3 1,4-Benzenediamine
106-51-4 2,5-Cyclohexadiene-1,4-dione
106-63-8 2-Propenoic acid, 2-methylpropyl ester
106-71-8 2-Propenoic acid, 2-cyanoethyl ester
106-74-1 2-Propenoic acid, 2-ethoxyethyl ester
106-83-2 Oxiraneoctanoic acid, 3-octyl-, butyl ester
106-84-3 Oxiraneoctanoic acid, 3-octyl-, octyl ester
106-87-6 7-Oxabicyclo[4.1.0]heptane, 3-oxiranyl-
106-88-7 Oxirane, ethyl-
106-89-8 Oxirane, (chloromethyl)-
106-90-1 2-Propenoic acid, oxiranylmethyl ester
106-91-2 2-Propenoic acid, 2-methyl-, oxiranylmethyl ester
106-92-3 Oxirane, [(2-propenyloxy)methyl]-
108-10-1 2-Pentanone, 4-methyl-
108-31-6 2,5-Furandione
108-38-3 Benzene, 1,3-dimethyl-
108-39-4 Phenol, 3-methyl-
108-42-9 Benzenamine, 3-chloro-
108-45-2 1,3-Benzenediamine
108-70-3 Benzene, 1,3,5-trichloro-
108-88-3 Benzene, methyl-
108-90-7 Benzene, chloro-
108-94-1 Cyclohexanone
109-16-0 2-Propenoic acid, 2-methyl-, 1,2-ethanediylbis(oxy-2,1-ethanediyl) ester
110-86-1 Pyridine
111-40-0 1,2-Ethanediamine, N-(2-aminoethyl)-
114-49-8 Benzeneacetic acid, .alpha.-(hydroxymethyl)-, 9-methyl-3-oxa-9-azatricyclo[3.3.1.02,4]non-7-yl ester, hydrobromide, [7(S)-(1.alpha.,2.beta.,4.beta.,5.alpha.,7.beta.)]-
115-27-5 4,7-Methanoisobenzofuran-1,3-dione, 4,5,6,7,8,8-hexachloro-3a,4,7,7a-tetrahydro-
115-28-6 Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, 1,4,5,6,7,7-hexachloro-
115-86-6 Phosphoric acid, triphenyl ester
116-15-4 1-Propene, 1,1,2,3,3,3-hexafluoro-
117-81-7 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester
117-84-0 1,2-Benzenedicarboxylic acid, dioctyl ester
118-79-6 Phenol, 2,4,6-tribromo-
119-06-2 1,2-Benzenedicarboxylic acid, ditridecyl ester
119-07-3 1,2-Benzenedicarboxylic acid, decyl octyl ester
120-82-1 Benzene, 1,2,4-trichloro-
121-39-1 Oxiranecarboxylic acid, 3-phenyl-, ethyl ester
121-45-9 Phosphorous acid, trimethyl ester
121-87-9 Benzenamine, 2-chloro-4-nitro-
122-07-6 Ethanamine, 2,2-dimethoxy-N-methyl-
122-60-1 Oxirane, (phenoxymethyl)-
123-31-9 1,4-Benzenediol
126-99-8 1,3-Butadiene, 2-chloro-
131-11-3 1,2-Benzenedicarboxylic acid, dimethyl ester
140-08-9 Ethanol, 2-chloro-, phosphite (3:1)
140-88-5 2-Propenoic acid, ethyl ester
141-32-2 2-Propenoic acid, butyl ester
141-38-8 Oxiraneoctanoic acid, 3-octyl-, 2-ethylhexyl ester
141-85-5 Benzenamine, 3-chloro-, hydrochloride
142-04-1 Benzenamine, hydrochloride
142-09-6 2-Propenoic acid, 2-methyl-, hexyl ester

142-90-5 2-Propenoic acid, 2-methyl-, dodecyl ester
145-73-3 7-Oxabicyclo[2.2.1]heptane-2,3-dicarboxylic acid
147-82-0 Benzenamine, 2,4,6-tribromo-
155-41-9 3-Oxa-9-azoniatricyclo[3.3.1.02,4]nonane, 7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9,9-dimethyl-, bromide, [7(S)-(1.alpha.,2.beta.,4.beta.,5.alpha.,7.beta.)]-
285-67-6 6-Oxabicyclo[3.1.0]hexane
286-20-4 7-Oxabicyclo[4.1.0]heptane
428-59-1 Oxirane, trifluoro(trifluoromethyl)-
470-67-7 7-Oxabicyclo[2.2.1]heptane, 1-methyl-4-(1-methylethyl)-
496-72-0 1,2-Benzenediamine, 4-methyl-
534-15-6 Ethane, 1,1-dimethoxy-
541-73-1 Benzene, 1,3-dichloro-
554-00-7 Benzenamine, 2,4-dichloro-
556-52-5 Oxiranemethanol
593-60-2 Ethene, bromo-
603-35-0 Phosphine, triphenyl-
608-27-5 Benzenamine, 2,3-dichloro-
608-93-5 Benzene, pentachloro-
615-05-4 1,3-Benzenediamine, 4-methoxy-
624-18-0 1,4-Benzenediamine, dihydrochloride
626-43-7 Benzenamine, 3,5-dichloro-
632-79-1 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-
634-66-2 Benzene, 1,2,3,4-tetrachloro-
634-90-2 Benzene, 1,2,3,5-tetrachloro-
634-93-5 Benzenamine, 2,4,6-trichloro-
635-22-3 Benzenamine, 4-chloro-3-nitro-
688-84-6 2-Propenoic acid, 2-methyl-, 2-ethylhexyl ester
689-12-3 2-Propenoic acid, 1-methylethyl ester
818-61-1 2-Propenoic acid, 2-hydroxyethyl ester
823-40-5 1,3-Benzenediamine, 2-methyl-
827-94-1 Benzenamine, 2,6-dibromo-4-nitro-
868-77-9 2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester
925-60-0 2-Propenoic acid, propyl ester
930-37-0 Oxirane, (methoxymethyl)-
1139-30-6 5-Oxatricyclo[8.2.0.04,6]dodecane, 4,12,12-trimethyl-9-methylene-, [1R-[1R*,4R*,6R*,10S*)]-
1241-94-7 Phosphoric acid, 2-ethylhexyl diphenyl ester
1309-64-4 Antimony oxide O3Sb2
1319-77-3 Phenol, methyl-
1321-64-8 Naphthalene, pentachloro-
1321-65-9 Naphthalene, trichloro-
1330-20-7 Benzene, dimethyl-
1330-61-6 2-Propenoic acid, isodecyl ester
1330-78-5 Phosphoric acid, tris(methylphenyl) ester
1335-87-1 Naphthalene, hexachloro-
1335-88-2 Naphthalene, tetrachloro-
1345-04-6 Antimony sulfide S3Sb2
1464-53-5 2,2'-Bioxirane
1663-39-4 2-Propenoic acid, 1,1-dimethylethyl ester
1817-73-8 Benzenamine, 2-bromo-4,6-dinitro-
1937-37-7 2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt
2082-81-7 2-Propenoic acid, 2-methyl-, 1,4-butanediyl ester
2156-96-9 2-Propenoic acid, decyl ester
2210-28-8 2-Propenoic acid, 2-methyl-, propyl ester
2223-82-7 2-Propenoic acid, 2,2-dimethyl-1,3-propanediyl ester
2234-13-1 Naphthalene, octachloro-
2238-07-5 Oxirane, 2,2'-[oxybis(methylene)]bis-
2358-84-1 2-Propenoic acid, 2-methyl-, oxydi-2,1-ethanediyl ester
2425-79-8 Oxirane, 2,2'-[1,4-butanediylbis(oxymethylene)]bis-
2426-08-6 Oxirane, (butoxymethyl)-
2426-54-2 2-Propenoic acid, 2-(diethylamino)ethyl ester
2455-24-5 2-Propenoic acid, 2-methyl-, (tetrahydro-2-furanyl)methyl ester
2461-18-9 Oxirane, [(dodecyloxy)methyl]-
2499-95-8 2-Propenoic acid, hexyl ester
2528-36-1 Phosphoric acid, dibutyl phenyl ester
2530-85-0 2-Propenoic acid, 2-methyl-, 3-(trimethoxysilyl)propyl ester
2602-46-2 2,7-Naphthalenedisulfonic acid, 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxy-, tetrasodium salt
2610-05-1 1,3-Naphthalenedisulfonic acid, 6,6'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[4-amino-5-hydroxy-, tetrasodium salt
2687-25-4 1,2-Benzenediamine, 3-methyl-
2855-19-8 Oxirane, decyl-
2867-47-2 2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester
2905-65-9 Benzoic acid, 3-chloro-, methyl ester
3076-04-8 2-Propenoic acid, tridecyl ester
3083-25-8 Oxirane, (2,2,2-trichloroethyl)-
3132-64-7 Oxirane, (bromomethyl)-
3194-55-6 Cyclododecane, 1,2,5,6,9,10-hexabromo-
3775-90-4 2-Propenoic acid, 2-methyl-, 2-[(1,1-dimethylethyl)amino]ethyl ester
3953-10-4 2-Propenoic acid, 2-ethylbutyl ester
4016-11-9 Oxirane, (ethoxymethyl)-
4016-14-2 Oxirane, [(1-methylethoxy)methyl]-
4835-11-4 1,6-Hexanediamine, N,N'-dibutyl-
5388-62-5 Benzenamine, 4-chloro-2,6-dinitro-
5455-98-1 1H-Isoindole-1,3(2H)-dione, 2-(oxiranylmethyl)-
5536-61-8 2-Propenoic acid, 2-methyl-, sodium salt
6033-05-2 Morphinan-3,6-diol, 7,8-didehydro-4,5-epoxy-17-methyl-(5.alpha.,6.alpha.)-, (Z)-9-octadecenoate (salt)
6106-46-3 Benzeneacetic acid, .alpha.-(hydroxymethyl)-, 9-methyl-3-oxa-9-azatricyclo[3.3.1.02,4]non-7-yl ester, [7(S)-(1.alpha.,2.beta.,4.beta.,5.alpha.,7.beta.)]-, compd. with methyl nitrate (1:1)
6106-81-6 Benzeneacetic acid, .alpha.-(hydroxymethyl)-, 9-methyl-3-oxa-9-azatricyclo[3.3.1.02,4]non-7-yl ester, N-oxide, hydrobromide, [7(S)-(1.alpha.,2.beta.,4.beta.,5.alpha.,7.beta.)]-
6283-25-6 Benzenamine, 2-chloro-5-nitro-
6369-59-1 1,4-Benzenediamine, 2-methyl-, sulfate
7320-37-8 Oxirane, tetradecyl-
7440-36-0 Antimony
7446-81-3 2-Propenoic acid, sodium salt
7534-94-3 2-Propenoic acid, 2-methyl-, 1,7,7-trimethylbicyclo[2.2.1]hept-2-yl ester, exo-
13048-33-4 2-Propenoic acid, 1,6-hexanediyl ester
13236-02-7 Oxirane, 2,2',2''-[1,2,3-propanetriyltris(oxymethylene)]tris-
13561-08-5 Oxirane, 2,2'-[[2-(oxiranylmethoxy)-1,3-phenylene]bis(methylene)]bis-
16110-89-7 Benzenesulfonic acid, 4-[(4,6-dichloro-1,3,5-triazin-2-yl)amino]-
16715-83-6 2-Propenoic acid, 2-methyl-, 2-[bis(1-methylethyl)amino]ethyl ester
17256-39-2 2-Propanamine, 1-chloro-N,N-dimethyl-, hydrochloride
17977-09-2 2-Propenoic acid, 2,2-dinitropropyl ester
24442-57-7 Ethanol, 1,2-dibromo-, acetate
25085-99-8 Oxirane, 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis-, homopolymer
25134-21-8 4,7-Methanoisobenzofuran-1,3-dione, 3a,4,7,7a-tetrahydromethyl-
25155-23-1 Phenol, dimethyl-, phosphate (3:1)
25550-14-5 Benzene, ethylmethyl-
25584-83-2 2-Propenoic acid, monoester with 1,2-propanediol
25637-99-4 Cyclododecane, hexabromo-
26444-49-5 Phosphoric acid, methylphenyl diphenyl ester
26447-14-3 Oxirane, [(methylphenoxy)methyl]-
26761-40-0 1,2-Benzenedicarboxylic acid, diisodecyl ester
26761-45-5 Neodecanoic acid, oxiranylmethyl ester
29761-21-5 Phosphoric acid, isodecyl diphenyl ester
32360-05-7 2-Propenoic acid, 2-methyl-, octadecyl ester
33791-58-1 2-Propenoic acid, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-indenyl ester
37853-59-1 Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis[2,4,6-tribromo-
51363-64-5 Phosphoric acid, diisodecyl phenyl ester
56803-37-3 Phosphoric acid, (1,1-dimethylethyl)phenyl diphenyl ester
66108-37-0 Phosphoric acid, 2,2-bis(bromomethyl)-3-chloropropyl bis[2-chloro-1-(chloromethyl)ethyl] ester

(e) A Preliminary Assessment Information Manufacturer's Report must be submitted by November 19, 1982 on confidential chemicals in the following categories. A chemical is confidential only if EPA upheld the respondent's claim of confidential identity for the TSCA Chemical Substance Inventory:

Alkyl phthalates—all alkyl esters of 1,2-benzene dicarboxylic acid (orthophthalic acid).

Aryl phosphates—phosphate esters of phenol or of alkyl-substituted phenols. Tri-aryl and mixed alkyl and aryl esters are included but tri-alkyl esters are excluded.

Glycidol derivatives—C_2H_3O-CH_2O-R where R is an alkyl, alkenyl, alkynyl, aryl, or acyl group. Any substituent or functional group may be present on the alkyl, etc. groups.

[FR Doc. 82-15956 Filed 6-21-82; 8:45 am]
BILLING CODE 6560-50-M